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Author:
U.S. Congress

Title:
Food, drugs and cosmetics

Place:
Washington, D.C.

Date:
1934

U. S. *Congress. Senate. Committee on commerce.*
Food, drugs, and cosmetics. Hearings before a subcommittee of the Committee on commerce, United States Senate, Seventy-third Congress, second session, on S. 1944, a bill to prevent the manufacture, shipment and sale of adulterated or misbranded food, drugs, and cosmetics and to regulate traffic therein; to prevent the false advertisement of food, drugs, and cosmetics, and for other purposes. December 7 and 8, 1933 ... Washington, U. S. Govt. print. off., 1934.
iv, 505 p. incl. tables. fold. pl. 23cm.
Printed for the use of the Committee on commerce.
Royal S. Copeland, chairman of subcommittee.
1. Food adulteration and inspection—U. S. 2. Drugs—Laws and legislation—U. S. 3. Cosmetics. I. Title.

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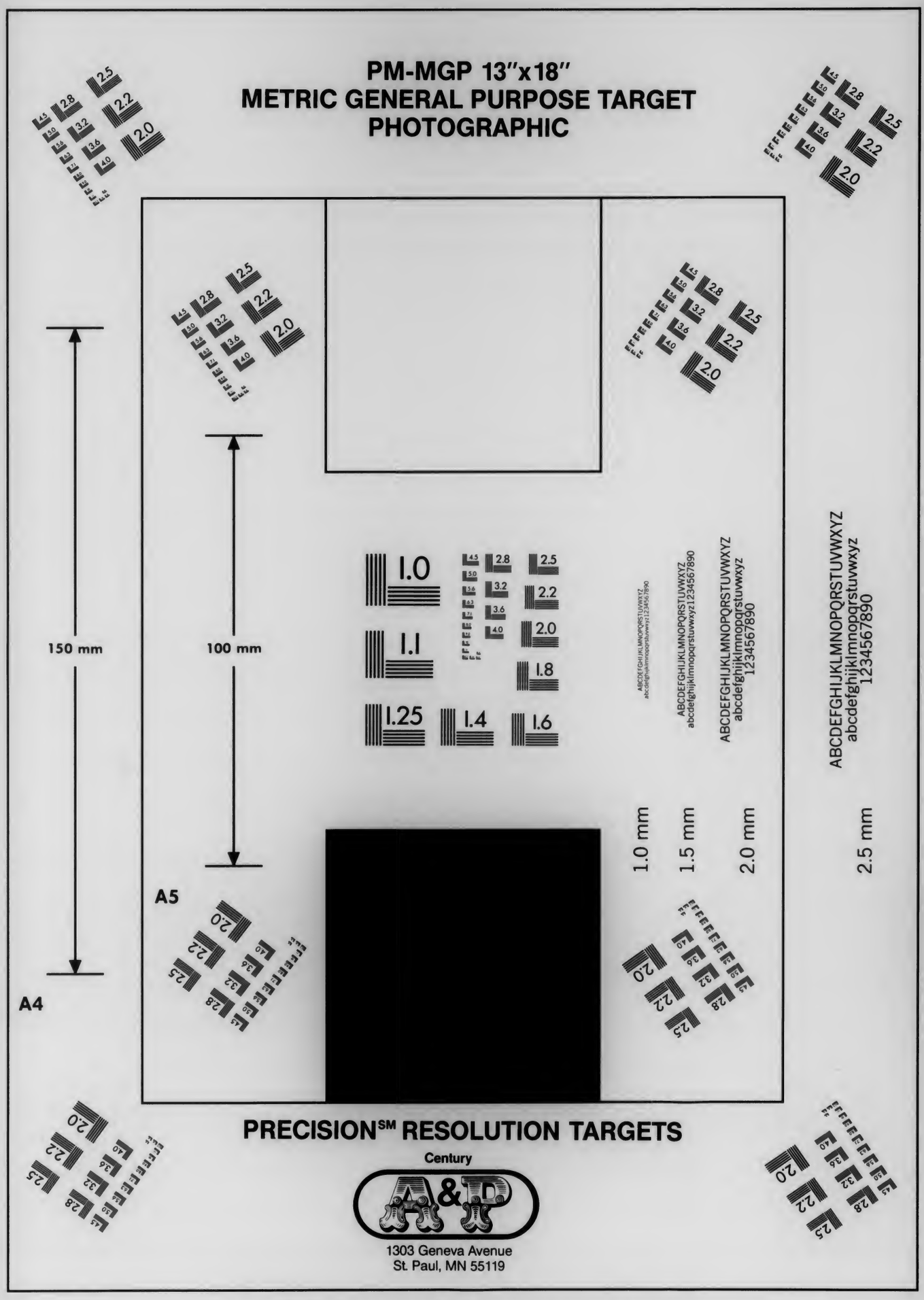

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FOOD, DRUGS, AND COSMETICS

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON COMMERCE UNITED STATES SENATE

SEVENTY-THIRD CONGRESS

SECOND SESSION

ON

S. 1944

A BILL TO PREVENT THE MANUFACTURE, SHIPMENT, AND SALE OF ADULTERATED OR MISBRANDED FOOD, DRUGS, AND COSMETICS, AND TO REGULATE TRAFFIC THEREIN; TO PREVENT THE FALSE ADVERTISEMENT OF FOOD, DRUGS, AND COSMETICS, AND FOR OTHER PURPOSES

DECEMBER 7 AND 8, 1933

Printed for the use of the Committee on Commerce

30360

UNITED STATES
GOVERNMENT PRINTING OFFICE
WASHINGTON : 1934

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FOOD, DRUGS, AND COSMETICS

THURSDAY, DECEMBER 7, 1933

UNITED STATES SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to call, in room 335 Senate Office Building, at 10:30 a.m., Senator Royal S. Copeland, presiding.

Present: Senators Copeland, McNary, and Caraway.

Senator COPELAND. The hearing will come to order, please. We have a crowded room. I am sorry we have not chairs enough for everybody. Perhaps we can secure enough after awhile to fill the room. We had to go from a room which we had arranged into this larger one, and even this seems to be crowded. So you will help us a lot if you will be as quiet as possible.

This is a hearing of the subcommittee of the Committee on Commerce to consider Senate Bill 1944, and the record at this point will show a copy of the bill.

(S. 1944 is as follows:) In the Senate of the United States, June 6 (calendar day, June 12), 1933.

Mr. Copeland introduced the following bill; which was read twice and referred to the Committee on Commerce.

A BILL to prevent the manufacture, shipment, and sale of adulterated or misbranded food, drugs, and cosmetics, and to regulate traffic therein; to prevent the false advertisement of food, drugs, and cosmetics, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Food and Drugs Act."

DEFINITIONS

SEC. 2. As used in this Act, unless the context otherwise indicates:

(a) The term "food" includes all substances and preparations used for, or entering into the composition of, food, drink, confectionery, or condiment for man or other animals.

(b) The term "drug" includes (1) all substances and preparations recognized in the United States Pharmacopoeia or National Formulary or supplements thereto; and (2) all substances, preparations, and devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations, other than food, and all devices, intended to affect the structure or any function of the body of man or other animals.

(c) The term "cosmetic" includes all substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of the person. Except as indicated in paragraph (b) (3) of this section, the definitions of food, drug, and cosmetic shall not be construed as mutually exclusive.

(d) The term "territory" means any territory or possession of the United States.

(e) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, or between points within the same State or Territory but through any place outside thereof, and (2) commerce and manufacture within the District of Columbia or the Canal Zone or within any territory not organized with a legislative body.

(f) The term "person" includes individual, partnership, corporation, and association.

(g) The term "Secretary" means the Secretary of Agriculture.

(h) The term "label" means the principal label or labels (1) upon the immediate container of any food, drug, or cosmetic, and (2) upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic.

(i) The term "labeling" includes all labels and other written, printed, and graphic matter, in any form whatsoever, accompanying any food, drug, or cosmetic.

(j) The term "advertisement" includes all representations of fact or opinion disseminated in any manner or by any means other than by the labeling.

(k) The term "in package form" includes wrapped meats enclosed in paper or other materials as prepared by the manufacturers thereof for sale.

ADULTERATION OF FOOD

SEC. 3. A food shall be deemed to be adulterated:

(a) (1) If it is or may be dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance prohibited, or in excess of the limits of tolerance prescribed, by regulations as hereinafter provided; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth; or (5) if it is the produce of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed of any poisonous or deleterious substance which may by contamination render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or create a deceptive appearance.

(c) If it is confectionery and bears or contains any alcohol, resinous glaze, or nonnutritive substance except coloring and flavoring.

(d) If it contains a coal-tar color other than one from a batch that has been certified by the Secretary in accordance with regulations as hereinafter provided

ADULTERATION OF DRUGS

SEC. 4. A drug shall be deemed to be adulterated:

(a) If it is or may be dangerous to health under the conditions of use prescribed in the labeling thereof.

(b) If its name is the same as or simulates a name recognized in the United States Pharmacopoeia or National Formulary or in any supplement thereto, official at the time the drug is introduced into the interstate commerce, or if it purports to be such a drug, and it fails to meet the definition, formula, and description set forth therein, or differs from the standard of strength, quality, or purity as as determined by the tests or methods of assay set forth therein; except that whenever tests or methods of assay have not been prescribed therein or such tests or methods of assay as are prescribed are found by the Secretary to be insufficient, he is hereby authorized to prescribe by regulations, tests, or methods of assay for determining whether or not such drug complies with such standards. No drug shall be deemed to be adulterated under this paragraph if its label bears, in the manner and form prescribed by regulations of the Secretary, a statement indicating wherein its strength, quality, and purity differ from the standard of strength, quality, and purity set forth in the United States Pharmacopoeia or National Formulary or in any supplement thereto, official at the time the drug is introduced into interstate commerce, as determined by the tests or methods of assay applicable under this paragraph.

(c) If it is not subject to the provisions of paragraph (b) of this section and its identity or strength differs from or its purity or quality falls below, that which it purports or is represented to possess.

(d) (1) If any substance has been mixed or packed therewith so as to reduce its quality or strength; or (2) if any substance has been substituted wholly or in part therefor.

ADULTERATION OF COSMETICS

SEC. 5. A cosmetic shall be deemed to be adulterated:

(a) If it is or may be injurious to the user under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

(b) If it bears or contains any poisonous or deleterious ingredient prohibited, or in excess of the limits of tolerance prescribed, by regulations as hereinafter provided.

MISBRANDING—GENERAL

SEC. 6. A food, drug, or cosmetic shall be deemed to be misbranded:

(a) If its labeling is in any particular false, or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetic.

(b) If in package form it fails to bear a label containing: (1) the name and place of business of the manufacturer, packer, seller, or distributor; and (2) an accurate statement of the quantity of the contents in such terms of weight, measure, or numerical count as may be prescribed by regulations of the Secretary: *Provided*, That under subdivision (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages of foods and cosmetics shall be established, by regulations prescribed by the Secretary: *And provided further*, That such classes of canned foods as the Secretary finds, after notice and hearing, are, in accordance with the practice of the trade, labeled in substantial quantities at establishments other than the establishments where processed or packed, shall be exempted by regulations from the requirements of this paragraph during transportation from the establishment where processed or packed to an establishment for labeling, if such articles are labeled in conformity with the provisions of this Act prior to removal from such labeling establishment.

(c) If any word, statement, or other information required on the label to avoid adulteration or misbranding under any provisions of this Act is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily intelligible to the purchasers and users of such articles under customary conditions of purchase and use.

MISBRANDING OF FOOD

SEC. 7. A food shall be deemed to be misbranded:

(a) If (1) its container is so made, formed, or filled as to mislead the purchaser, or (2) its contents fall below the standard of fill prescribed by regulations as hereinafter provided.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, except that no imitation shall be deemed to be misbranded under this paragraph if its label bears the word "imitation" in juxtaposition with and in type of the same size and prominent as the name of the food imitated.

(d) If it purports to be or is represented as a food for which a definition of identity has been prescribed by regulations as hereinafter provided, and (1) fails to bear on its label the name of the food defined in such terms as the regulations specify, or (2) fails to conform to the definition.

(e) If it purports to be or is represented as a food for which standards of quality have been prescribed by regulations as hereinafter provided, and (1) fails to state on its label, if so required by the regulations, a standard of quality in such terms as the regulations specify, or (2) falls below the standard stated on the label.

(f) If it purports to be or is represented as a food for which no definition of identity has been prescribed by regulations as hereinafter provided, and its label fails to bear (1) the common or usual name of the food, if any there be, and (2) the common or usual name of each ingredient thereof in order of predominance by weight; except that spices, flavors, and artificial colors may be designated as such without naming each spice, flavor, or artificial color. The Secretary is hereby authorized to prescribe by regulations requirements for such further information on the label thereof as he may deem necessary to protect the public from deception.

MISBRANDING OF DRUGS

SEC. 8. A drug shall be deemed to be misbranded:

(a) (1) If its labeling bears the name of any disease for which the drug is not a specific cure but is a palliative, and fails to bear in juxtaposition with such name and in letters of the same size and prominence a statement that the drug is not a

cure for such disease; or (2) if its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.

(b) If it is for internal use by man and contains any quantity of any of the following narcotic or hypnotic substances: Alpha cucaine, barbital, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, morphine, opium, paraldehyde, peyote, sulphonmethane, or any narcotic or hypnotic derivative therefrom by actual or theoretical chemical reaction, and its label fails to bear the name and a statement, in the manner and form prescribed by regulations promulgated by the Secretary, of the quantity or proportion of such substance or derivative in juxtaposition with the statement "Warning—May be habit forming." The Secretary is hereby authorized, by regulations prescribed after notice and hearing, to designate as narcotics or hypnotics within the meaning of this pargaraph such other substances as he may find to possess narcotic or hypnotic properties.

(c) If it contains any quantity of ethyl alcohol, ethyl ether, or chloroform, and its label fails to bear a statement, in the manner and form prescribed by regulations of the Secretary, of the quantity or proportion of such substance.

(d) If it is not subject to the provisions of paragraph (i) of this section, and its labeling fails to bear complete and explicit directions for use: Provided, That the Secretary may by regulation exempt any drug from any requirement of this paragraph if he deems such requirement unnecessary for the protection of public health.

(e) If it is not subject to the provisions of paragraph (b) of section 4 and its label fails to bear (1) the common name of the drug, if any there be, and (2) the name and quantity or proportion of each medicinal or physiologically active ingredient thereof. The Secretary is hereby authorized to prescribe by regulations requirements for such further information on the label of such drug as he may deem necessary to protect the public health.

(f) If its name is the same as, or simulates, a name recognized in the United States Pharmacopoeia or National Formulary or any supplement thereto official at the time such drug is introduced into interstate commerce, and it is not packaged and labeled as prescribed therein.

(g) If it is a drug liable to deterioration, and is not packaged in such form or manner, or if its label fails to bear a statement of such precautions, as the Secretary may prescribe by regulations, after notice and hearing, for the protection of public health. The Secretary is hereby authorized to designate by regulations, prescribed after notice and hearing, as drugs liable to deterioration within the meaning of this paragraph, such drugs as he may find to be liable to deterioration.

(h) (1) If its container is so made, formed, or filled as to mislead the purchaser; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(i) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for any use on or within the human or animal body and its labeling fails to bear a statement of each such use and, plainly and conspicuously and in juxtaposition therewith, the method and duration of application necessary to kill all micro-organisms in the vegetative or other active form with which it comes in contact when so used; except that no drug shall be deemed to be misbranded under this paragraph if its label bears a statement that it is a germicide, bactericide, disinfectant, or antiseptic for specific kinds of micro-organisms only, and its labeling bears a statement of each purported or represented use and, plainly and conspicuously and in juxtaposition therewith, the conditions, including duration of application, under which the drug kills all such specific kinds of micro-organisms in the vegetative or other active form with which it comes in contact when so used.

FALSE ADVERTISEMENT

SEC. 9. (a) An advertisement of a food, drug, or cosmetic shall be deemed to be false if in any particular it is untrue, or by ambiguity or inference creates a misleading impression regarding such food, drug, or cosmetic.

(b) An advertisement of a drug shall also be deemed to be false if it includes (1) the name of any disease for which the drug is not a specific cure but is a palliative, and fails to state with equal prominence and in immediate connection with such name that the drug is not a cure for such disease; or (2) any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.

(c) To discourage the public advertisement for sale in interstate commerce of drugs for diseases wherein self-medication may be especially dangerous, or patently contrary to the interests of public health, any advertisement of a drug representing it directly or by ambiguity or inference to have any effect in the treatment of any of the following diseases shall be deemed to be false: Albuminuria, appendicitis, arteriosclerosis, blood poison, bone diseases, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis, prostate gland disorders, pyolitis, scarlet fever, sexual impotence, sinus infections, smallpox, tuberculosis, tumors, typhoid, uremia, veneral diseases, whooping cough; except that no advertisement shall be deemed to be false under this paragraph if it is disseminated to members of the medical and pharmacological professions only or appears in scientific periodicals: *Provided*, That whenever the Secretary, after notice and hearing, determines that an advance in medical science has made any type of self-medication safe as to any of the diseases enumerated above, he may by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as he may deem necessary in the interests of public health: *Provided further*, That whenever the Secretary, after notice and hearing, determines that self-medication for diseases other than those herein named may be especially dangerous, or patently contrary to the interests of public health, he is hereby authorized to promulgate regulations designating such other diseases as diseases within the meaning of this paragraph: *Provided further*, That this paragraph shall not be construed as indicating that self-medication for diseases other than those named herein or designated by regulations of the Secretary under the authority hereof is safe or efficacious.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND COSMETICS AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 10. (a) If the Secretary finds that the presence of an added poisonous or added deleterious substance in or on food or cosmetics is or may be injurious to the health taking into account other ways in which the consumer or user may partake of or be exposed to the same or other poisonous or deleterious substances, then the Secretary shall by regulations promulgated after notice and hearing prohibit such added substances in or on food or cosmetics, or establish tolerances limiting the amount therein or thereon, to such extent as he may deem necessary to prevent such injury to health.

(b) The Secretary is hereby authorized to make regulations, after notice and hearing, for the certification of coal-tar colors which he finds to be harmless for use in food.

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 11. The Secretary is hereby authorized to fix, establish, and promulgate definitions of identity and standards of quality and fill of container for any food. Whenever the Secretary deems that for the purposes of this Act any such definition or standard should be established for any food, he shall give notice of a proposed definition or standard and of the time and place of a public hearing to be held thereon not less than thirty days after the date of such notice. After such public hearing the Secretary may fix, establish, and promulgate a definition or standard for such food. The definition or standard so promulgated shall become effective on a date fixed by the Secretary, which date shall not be prior to ninety days after its promulgation. Any such definition or standard may be amended or repealed after notice and hearing as hereinbefore provided, and if amended or repealed the amendment or repeal shall become effective in the manner and at the time hereinbefore provided.

PERMIT FACTORIES

SEC. 12. (a) Whenever the Secretary finds that the distribution in interstate commerce of any class of food, drugs, or cosmetics may, by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health, and such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he is authorized, after notice and hearing, to make such regulations governing the conditions of manufacture, processing, or packing as he deems necessary to protect the public health, and

requiring manufacturers, processors, and packers of such class of articles to hold a permit conditioned on compliance with such regulations.

(b) The Secretary is authorized to issue such permits for such periods of time as he may be regulations prescribe and to make regulations governing the issuance and renewal thereof. The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The Secretary may reinstate the permit whenever, after hearing and an inspection of the establishment, it is found that adequate measures have been taken to comply with the conditions of the original permit.

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

FACTORY INSPECTION

SEC. 13. (a) In order adequately to regulate interstate commerce in food, drugs, and cosmetics, and enforce the provisions of this Act, officers or employees duly designated by the Secretary, after first obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter any factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed, or held for shipment in interstate commerce or are held after such shipment, or to enter any vehicle being used to transport such food, drugs, or cosmetics, in interstate commerce; and (2) to inspect such factory, warehouse, establishment, or vehicle and all equipment, methods, processes, finished and unfinished materials, containers, and labels there used or stored.

(b) (1) The several district courts of the United States are hereby vested with jurisdiction to restrain by injunction temporary or permanent, the shipment in interstate commerce or delivery after receipt in interstate commerce of any food, drug, or cosmetic from or by any factory, warehouse, establishment, or vehicle, if the owner, operator, or custodian thereof has denied to officers or employees duly designated by the Secretary permission so to enter and inspect such factory, warehouse, establishment, or vehicle and equipment, methods, processes, finished and unfinished materials, containers, and labels there used or stored. Whenever such permission is granted, the injunction issued pursuant to this paragraph shall be dissolved, or may be continued in force subject to such conditions governing the inspection as the court may order; and (2) violation of any such injunction may be summarily tried and punished by the court as a contempt. Such contempt proceedings may be instituted by order of the court or by the filing of an information by the United States attorney.

RECORDS OF INTERSTATE SHIPMENT

SEC. 14. For the purpose of enforcing the provisions of this Act, carriers subject to the Interstate Commerce Act, as amended (U.S.C., title 49), and other carriers engaged in interstate commerce, and persons receiving food, drugs, or cosmetics in interstate commerce, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee to have access to and to copy all records showing the movement in interstate commerce of any food, drug, or cosmetic, and the nature, kind, quantity, shipper, and consignee thereof, and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any record so requested: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.

INVESTIGATIONS AND INSTITUTION OF PROCEEDINGS

SEC. 15. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department of Agriculture or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary.

(b) It shall be the duty of each United States attorney to whom the Secretary reports any violation for institution of criminal, libel for condemnation, or other proceedings under this Act, or to whom any health, food, or drug officer of any State or Territory, or political subdivision thereof, presents evidence satisfactory to the United States attorney of any such violation, to cause appropriate proceedings to be instituted in the proper courts of the United States without delay. All suits instituted under this Act shall be by and in the name of the United States.

(c) The Secretary shall, before reporting any violation of this Act to the United States Attorney for institution of criminal proceedings thereunder, afford due notice and opportunity for hearing to interested parties in accordance with such regulations as the Secretary shall prescribe. The report of the Secretary to the United States Attorney for the institution of criminal proceedings under this Act shall be accompanied by findings of the appropriate officers and employees duly authenticated under their oaths.

SEIZURE

SEC. 16. (a) Any article of food, drug, or cosmetic in interest commerce that is adulterated or misbranded or that has been manufactured, processed, or packed in a factory or establishment, the operator of which did not, at the time of manufacture, processing, or packing, hold a valid permit if so required by regulations under section 12, shall be liable to be proceeded against while in interstate commerce or at any time thereafter on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. The article shall be liable to seizure (1) by process pursuant to the libel, or (2) if a chief of station or other officer of the Food and Drug Administration, duly designated by the Secretary, has probable cause to believe that the article is so adulterated as to be imminently dangerous to health, then by order of such officer, issued under his oath of office, particularly describing the article to be seized, the place where located, and the officer or employee to make the seizure. In case of seizure pursuant to any such order, the jurisdiction of the court shall attach upon such seizure. Any article seized pursuant to any such order shall thereupon be promptly placed in the custody of the court and a libel of information shall be promptly filed for condemnation thereof.

(b) If recovery is had in any suit or proceeding against any officer or employee by reason of a seizure pursuant to any such order, and the court certifies that there is probable cause for the acts done by such officer or employee, or that he acted under the direction of the Secretary or a duly designated officer of the Food and Drug Administration, no execution shall issue against such officer or employee, but the amount so recovered shall, upon final judgment, be provided for and paid out of appropriations for the administration of this Act.

(c) The court may, by order at any time before trial, allow any party to a condemnation proceeding to obtain a representative sample of the article seized.

(d) Any article of food, drug, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article of food, drug, or cosmetic shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the party obtaining release of the article under bond. Any article condemned by reason of the manufacturer, processor, or packer not holding a valid permit when so required by regulations under section 12 shall be disposed of by destruction.

(e) The proceedings in cases under this section shall conform, as nearly as may be, to the proceedings in admiralty; except that either party may demand trial by jury of any issue of fact joined in any such case.

(f) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any intervening as claimant of the article.

PENALTIES

SEC. 17. (a) The following Acts are hereby prohibited:

(1) The introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded.

(2) The receipt in interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded and the delivery or proffered delivery thereof in the original unbroken package for pay or otherwise.

(3) The dissemination of any false advertisement by radio broadcast, United States mails, or in interstate commerce for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics.

(4) The dissemination of a fasle advertisement by any means for the purpose of inducing, directly or indirectly, the sale of food, drugs, or cosmetics in interstate commerce.

(5) The introduction into interstate commerce of any food, drug, or cosmetic if the manufacturer, processor, or packer does not hold a valid permit when so required by regulations under section 12.

(6) The refusal to permit access to or copying of any record as required by section 14.

(b) Any person who violates or causes to be violated any of the provisions of paragraph (a) of this section shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not less than $100 nor more than $1,000, or both such imprisonment and fine; and for a second or subsequent offense imprisonment for not more than two years, or a fine of not less than $500 nor more than $3,000, or both such imprisonment and fine.

(c) Notwithstanding the provisions of paragraph (b) of this section, in case of a willful offense the penalty shall be imprisonment for not less than six months nor more than three years, or a fine of not less than $1,000 nor more than $10,000 or both such imprisonment and fine.

(d) No person acting in the capacity of publisher, advertising agency, or radio-broadcast licensee shall be prosecuted under paragraphs (b) or (c) of this section for disseminating a false advertisement if, on request of an officer or employee duly designated by the Secretary, he furnishes the name and post-office address of the person who contracted for or caused him to disseminate such advertisement.

(e) No dealer shall be prosecuted under paragraph (b) of this section if he establishes a guaranty or undertaking signed by the person residing in the United States from whom he received the article of food, drug, or cosmetic, or the advertising copy therefor, to the effect that such person assumes full responsibility for any violation of this Act, designating it, which may be incurred by the introduction of such article into interstate commerce or by the dissemination of such advertising. To afford protection, such guaranty or undertaking shall contain the name and address of the person furnishing such guaranty or undertaking, and such person shall be amenable to the prosecution and penalties which would attach in due course to the dealer under the provisions of this Act.

(f) Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized by the provisions of sections 12 and 22 of this Act or regulation thereunder, shall be guilty of a misdemeanor, and shall, on conviction thereof be subject to imprisonment for not more than one year, or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine.

LIABILITY OF CORPORATE OFFICERS

SEC. 18. (a) When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, or agent acting for or employed by any person, within the scope of his employment or office, shall in every case be deemed to be the act, omission, or failure of such person, as well as that of the officer, employee, or agent.

(b) Whenever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation.

INJUNCTION PROCEEDINGS

SEC. 19. (a) The repetitious introduction into interstate commerce of any adulterated or misbranded food, drug, or cosmetic, or the repetitious dissemination by radio broadcast or United States mail or in interstate commerce of false advertising of any food, drug, or cosmetic, by any person, is hereby declared to be a public nuisance. In order to avoid multiplicity of criminal proceedings with respect to such person or libel for condemnation proceedings with respect to the

food, drug, or cosmetic, the district courts of the United States are hereby vested with jurisdiction to restrain by injunction, temporary or permanent, any person from continuing any such nuisance. In such injunction proceedings it shall not be necessary to show on the part of such person an intent to continue such nuisance.

(b) Violation of any such injunction may be summarily tried and punished by the court as a contempt. Such contempt proceedings may be instituted by order of the court or by the filing of an information by the United States attorney; and process of the court for the arrest of the violator may be served at any place in the United States or subject to its jurisdiction.

IMPORTS

SEC. 20 (a) The Secretary of the Treasury shall deliver to the Secretary of Agriculture upon his request, from time to time, samples of food, drugs, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) any false advertisement of such food, drug, or cosmetic has been disseminated in the United States within three months prior to the date such article is offered for import, or (2) such article has been manufactured, processed, or packed under unsanitary conditions, or (3) such article is adulterated or misbranded within the meaning of this act, then such article shall be refused admission.

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon, and on refusal to return such article or any part thereof for any cause to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose said consignee shall forfeit the full amount of the bond as liquidated damages.

(c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

PUBLICITY

SEC. 21. The Secretary shall cause to be published periodically a report summarizing all judgments, decrees, and orders which have been rendered, and all proceedings instituted and seizures made, including the nature of the charge and the disposition thereof. The Secretary shall cause to be disseminated such information regarding any food, drug, or cosmetic as he deems necessary in the interests of public health and for the protection of the consumer against fraud.

VOLUNTARY INSPECTION SERVICE

SEC. 22. The Secretary, upon application of any manufacturer or packer of any food, drug, or cosmetic sold in interstate commerce, may at his discretion, designate supervisory inspectors to examine and inspect all premises, equipment, methods, materials, containers, and labels used by such applicant in the production of food, drugs, or cosmetics. If upon such examination the food, drug, or cosmetic is found to conform to the requirements of this Act, the applicant may be authorized, in accordance with regulations prescribed by the Secretary, to mark the food, drug, or cosmetic so as to indicate such conformity and such other facts relating to the identity or quality of the food, drug, or cosmetic as the regulations may provide. Services to any applicant under this section shall be rendered only upon the payment of fees to be fixed by regulations of the Secretary in such amount as to cover the cost of the supervisory inspection and examination, together with the reasonable costs of administration (including costs of establishing under section 11 additional definitions and standards for the purposes of this section) incurred by the Secretary in carrying out this section Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary for expenditures incurred in carrying out this section.

GENERAL ADMINISTRATIVE PROVISIONS

SEC. 23. (a) The Secretary of Agriculture is authorized to prescribe such regulations as he may deem necessary for the efficient enforcement of the functions vested in him by the provisions of this Act) other than the provisions of sec. 20), including regulations with the force and effect of law as to notice and conduct of hearings by the Secretary. The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe such regulations as they may deem necessary for the efficient enforcement of the provisions of Section 20. Regulations prescribed under this Act shall be promulgated in such manner and take effect at such time as the Secretary of Agriculture (and, in appropriate cases, the Secretary of the Treasury) shall determine.

(b) For the efficient administration of the provisions of this Act, the provisions, including penalties, of sections 9 and 10 of the Federal Trade Commission Act, approved September 26, 1914 (U.S.C., title 49, secs. 49 and 50), are made applicable to the jurisdiction, powers, and duties of the Secretary under this Act and to any person subject to the provisions of this Act, whether or not a corporation.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose. The findings of fact by the Secretary shall be conclusive if in accordance with law.

LIABILITY FOR PERSONAL INJURIES

SEC. 24. A right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act.

SEPARABILITY CLAUSE

SEC. 25. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

SEC. 26. (a) This Act shall take effect six months after the date of approval. The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., title 21, secs. 1–15), shall remain in force until such effective date, and is hereby repealed effective upon such date: *Provided*, That upon the approval of this Act and before its effective date the Secretary is authorized to conduct hearings and to promulgate regulations, definitions, and standards under the provisions hereof which shall become effective on or after the effective date of this Act as the Secretary shall direct.

(b) The provisions of this Act shall not be held to modify or repeal but shall be held in addition to the provisions of the following Acts, as amended: The Tea Import Act, approved March 2, 1897 (U.S.C., title 21, secs. 41–50); the Virus Act, approved March 4, 1913 (U.S.C., title 21, secs. 151–158); the United States Grain Standards Act, approved August 11, 1916 (U.S.C., title 7, secs. 70–87); the Insecticide Act, approved April 26, 1910 (U.S.C., title 7, secs. 121–134); the Import Milk Act, approved February 13, 1927 (U.S.C., title 21, secs. 141–149); the Caustic Poison Act, approved March 4, 1927 (U.S.C., title 15, secs. 401–511); the Virus, Serum, Toxin, and Antitoxin Act, approved July 1, 1902 (U.S.C., title 42, secs. 141–148).

We wish first to call upon the Secretary of Agriculture, Mr. Wallace, who will present the views of the Department of Agriculture which has in charge the particular work of the Food and Drugs Bureau. Mr. Wallace, we shall be glad to hear from you.

STATEMENT OF HON. HENRY A. WALLACE, SECRETARY OF AGRICULTURE

Mr. WALLACE. I regret that owing to an engagement made several weeks ago, before I knew of this hearing, I must be across town by 11 o'clock, which will necessitate my reading this prepared statement rather rapidly and making my informal remarks very short.

The Department of Agriculture officially endorses the bill, S. 1944, which you are considering. I personally give approval.

I must say candidly that I am not prepared to discuss its detailed provisions. I shall leave that responsibility to officials of the Food and Drug Administration.

My own time has been taken up so exclusively with emergency matters in the field of agricultural and national recovery that I have not had an opportunity to give this measure the degree of study and active support it deserves. I am none the less interested in its broad purposes. I have kept constantly in touch with it through the Assistant Secretary and the Solicitor of the Department. Along with these officials, I wish to express my unqualified approval of the public-spirited work that has been done for years by Mr. Walter G. Campbell, Chief of the Food and Drug Administration, and by his associates, and that has resulted in the bill you are now considering.

You no doubt know that Mr. Campbell and many of his associates have been engaged in guarding the food and drug supply of this country almost since Federal regulation started in 1906. They have written into this revision the needs that have become apparent during that time. Tnere is nothing new or startling about most of the changes. Most of them have been recommended time and again by responsible officials charged with the duty of protecting the public health.

The Food and Drugs Act of 1906 was something of an innovation in Federal legislation. It was bitterly opposed at the time by many interests which subsequently became some of its strongest supporters. The 1906 law, as far as it goes, has been effective in controlling adulterated and misbranded foods and drugs; it has served to correct many of the abuses that existed at the time of its enactment. But present-day conditions in the food and drug businesses are very different from what they were more than a quarter of a century ago.

There is a greatly increased traffic in foods and drugs today as compared to 1906. The cosmetic industry has become of first importance, whereas when the present law was written the cosmetic industry was in its infancy. The effectiveness with which a worthless or dangerous product can be sold today through modern advertising methods was not an acute problem in 1906. New narcotic and habit-forming drugs have appeared on the market. Totally new food constituents and important nutrition elements like the vitamins have been discovered.

These developments call for new methods of control. Then, too, during the past 27 years of enforcement, officials have had driven home to them many weaknesses and loopholes in the present law. For example, the necessity of the Government's proving that a drug product is both falsely and fraudulently represented has proved a great hindrance to effective enforcement.

I doubt that anyone will wish to appear before this committee in defense of the many abuses which cannot be remedied under existing legislation; there is too much grim evidence of the tragic effects that almost daily result from the Government's inability to prevent the shipment and sale of dangerous and worthless products. The Department will place some of this evidence before you, because only through a clear recognition of the abuses can we secure the right kind of remedial legislation.

The Department has not submitted to you an idealistic measure. On the contrary, we are convinced that we have presented for consideration a thoroughly practical, enforceable measure that is essential if we are to be expected to afford real consumer protection. The bill has been drawn, I understand, in such a way as to preserve to the greatest extent possible the language of the present statute and the effect of appellate decisions made during the past quarter of a century. In addition to preserving the worthy features of the present law, the bill proposes a number of changes in enforcement powers and policies, including these:

Cosmetics are brought within the scope of the statute;

Mechanical devices, offered for curative purposes, and devices and preparations claimed to bring about changes in the structure of the body are included within the purview of the bill;

False advertising of foods, drugs, and cosmetics is prohibited;

Definitely informative labeling is required;

A drug which is, or may be, dangerous to health under the conditions of use prescribed in its labeling is classed as adulterated;

The promulgation of definitions and standards for foods, which will have the force and effect of law, subject, of course, to court review, is prescribed;

The prohibition of added poisons in foods or the establishment of safe tolerances therefor is provided for;

The operation of factories under Federal permit is prescribed where protection of the public health cannot otherwise be effected;

More effective methods for the control of false labeling and advertising of drug products are provided; and

More severe penalties, as well as injunctions in the case of repeated offenses, are prescribed.

I think it is generally understood that this bill is intended primarily to protect consumers. At the same time it should operate in the interest of all honest manufacturers.

Agriculture has special reasons for favoring it. Farmers are interested as producers and users of food, as extensive users of package medicines, and as almost exclusive users of veterinary medicines and stock feeds. Agriculture is interested in any measure that helps the consumer obtain food which is unadulterated and honestly represented.

Since this bill was introduced in the closing days of the last session of Congress, the Department has received thousands of letters about it—some from consumers who approved it as it now stands; some from physicians and others who feel that it does not go nearly far enough in providing protection; and some from interested manufacturers who have much fault to find with specific provisions. But if the Department has received a single communication that disagrees with the intent of the bill, with its broad principles, I have not seen it.

I should like to repeat that I endorse this bill for the Department. I know that our representatives who are familiar with its every aspect will be glad to give you any information which may be useful to you. Mr. Campbell and others of the Food and Drug Administration will remain here for whatever testimony you wish to receive from them.

I would like to offer these general observations growing out of my previous connection with the publishing and advertising business: It is my observation, based on past experience, and to some extent on more recent contact with the broader minded advertising and publishing people, that they take the view that there is so much consumer purchasing power centering around a given publication; that is, so much purchasing power possessed by the readers of a given publication, if that purchasing power is soaked up by expenditures for things which are harmful to the readers, there is that much less money to be spent for the things that are worthwhile to the readers, and there is that much less efficiency on the part of the readers of that publication.

I say that the broader minded people in the field of publication and advertising, in my opinion, are ready to take that broad general fundamentally sound social point of view. I am not speaking, as you can well understand, in any representative capacity for these people. I want that to be clearly understood. But because of my previous contact before coming to Washington on March 4 last, I want to give that as my impression of the attitude of the broader gaged people of the publishing and advertising business. One gentleman particularly has informed me that that was his attitude.

Now, that does not mean—for fear I may represent these people—that they are in complete harmony with every detail of the bill. They have suggested certain things that they would like to see changed; but it does mean that they stand on that broad, social principle to which it seems to me no broad-gaged person can take exception, that advertising should be safeguarded.

Now, it is true that as long as advertising is allowed to go as it is, with even the people in the advertising business who have the highest ideals in the world, seeing this "chiseling" coming in from a great many sources, that that tends to lower their standards; and for that reason it seems to me that the advertising people themselves should be most happy to have some standard to which advertising can be referred.

Senator COPELAND. We are very much obliged to you, Mr. Secretary.

Secretary Wallace has suggested that Mr. Walter G. Campbell, Chief of the Food and Drug Administration of the Department of Agriculture, be permitted to present an explanation of the pending bill in detail. Mr. Campbell.

STATEMENT OF WALTER G. CAMPBELL, CHIEF, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF AGRICULTURE

Mr. CAMPBELL. Mr. Chairman, we in the Department of Agriculture would have preferred, for sentimental and other reasons, to have had this bill appear as an amendment to the Food and Drugs Act instead of a measure to supplant that law.

May I say that in the framing of this bill there was no sense of abandonment at all of the present act. There is an ample realization of the benefits that the present Food and Drugs Act has conferred upon society. It is a statute that was passed for the protection of the consumer. As the Secretary of Agriculture has said, it incidentally protects the honest manuacturer; but that bill, like most legislation, was a compromise measure; it represented not everything that the proponents of the law wanted, and carried more than the opponents of the measure were willing to give.

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Twenty-seven years of experience in the enforcement of that act has demonstrated adequately and emphatically its limitations for proper protectoin of the public. In the draft of the pending bill there has been an attempt made to preserve all of the worthy qualities and features of the existing law and to supplement it in those instances where weaknesses have been indicated by court decisions and by actual experience.

As an illustration of one of the most pronounced limitations of the existing act, I call your attention, Mr. Chairman, to section 8 of the law, which states that no product shall be deemed to be adulterated, or misbranded, if it does not contain an added poisonous, deleterious ingredient; provided it is plainly labeled, branded, or tagged, so as to indicate that it is a compound, imitation, or blend.

It also makes an exemption, in the case of articles which may be from time to time sold under their own distinctive names.

Here is a product labeled "Bred Spred", which has the appearance of a preserve. Investigation of the retail market showed that it was actually sold as a preserve or as a jam, but it contains less than one half the amount of fruit required by the standard recognized by the Department for such products. The sale to the public of an article of this sort, bearing in mind that the most expensive ingredient in jams and preserves is the fruit content, is obviously a fraud upon the public. To the extent that such products can be prepared and sold, containing less than one half the amount of fruit expected by the purchaser, used by manufacturers generally and established as a trade custom, it likewise deprives the farmer of a legitimate market for his fruit.

Compare the article marked as "Bred Spred" with this standard jam or preserve, which contains the full 45 percent of fruit required. Their appearance is identical. They are sold in glass containers which characterize this class of products; and I submit to you that the consumer, even though a discriminating buyer, in almost every instance would be perfectly willing to accept either as a pure preserve. As a matter of fact, the price for which the article known under the distinctive name "Bred Spred" was sold, was only slightly less than that of the product sold under the label of pure preserves.

This bill S. 1944 as framed eliminates that objectionable provision of the act which makes it possible, by the employment of some fanciful designation like the term "Bred Spred" to market a product under the legal assurance that it will be subject to none of the prohibitions of the act as applied to all types of foods and drugs, with the single exception that it must contain no added poisonous ingredients.

The article sold as "Bred Spred" under the distinctive name, therefore, could be composed of moldy, decomposed, and decayed fruits, and still there would be no power accruing to the Government by which its sale could be prevented, since such decomposed material could not be shown to be injurious to health.

In drafting this measure we have undertaken, as far as it was possible to do so, to preserve the general scheme of the original act. There has been a definition of adulteration and of misbranding. There has been a more orderly arrangement of both the substantive and the implementing provisions.

It was found, soon after we undertook to make provision for the elimination of those sections of the act containing jokers, as in the case that I have demonstrated, and to correct the existing deficiencies of the law, that a mere amendment of the present statute presented, from a drafting standpoint, an impossible task. That is the reason the bill appears as one to supplant entirely the present act; but, as I have said, we have sought to preserve all of the worthwhile features of that law, and to make provision for the badly needed additional requirements which the experience of almost 30 years in the enforcement of the act has shown should be provided if the public is to be properly protected.

Senator COPELAND. Is the same language used in this bill as appears in the original act?

Mr. CAMPBELL. The same language is used in many places. In other places, advantage has been taken of interpreting court decisions to make more plain and more definite to the agencies subject to the terms of the law just what the significance of the statements now in the act may be. We will take this up from time to time as we proceed.

The first section of the bill is devoted to definitions. The definition of the term "food" is precisely that of the present act, with the exception in line 9, on page 1, of the words "or entering into the composition of." Those words are not to be found in the existing definition. The reason for the incorporation of those words was to make certain of jurisdiction in the case of products like cream of tartar and phosphates which are not in and of themselves food but are employed so extensively in the manufacture of food, such as baking powders.

The definition of the term "drug" has been widened. In the present act that term is defined as including all medicines and preparations recognized in the United States Pharmacopoeia for internal or external use and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or animal.

There has been raised in that connection a question about the meaning of the words "substance or mixture of substances", whether the present definition of the term "drug" is sufficiently broad to include sutures, surgical dressings and the like. The importance of such products must be apparent immediately. We have found some such products on the market that were not sterile and have taken action, whether justified by the terms of the present law or not.

Senator COPELAND. Would that go so far as to cover the use of a truss or implements of that sort?

Mr. CAMPBELL. Under this particular definition it would. The words "device" in line 6, on page 2, is the word of the new definition which extends the scope of the law to cover not only surgical dressings but trusses or any other mechanical appliance that might be employed for the treatment of disease or intended for the cure or mitigation or prevention of disease.

Senator COPELAND. Would it refer to ultraviolet lights and various instruments of that sort?

Mr. CAMPBELL. It would. The third portion of the definition of the term drugs, all substances and preparations, other than food, and all devices intended to affect the structure or any function of the body of man or other animal, is admittedly an inclusive, a wide definition.

The purpose of the drafters of this bill in the formulation of that part of this section, Mr. Chairman, was to make possible the regulation of a great many products that have been found on the market that cannot be alleged to be treatments for diseased conditions.

I have in mind such products as antifat remedies. Obesity may not be a disease. There has been lately a tendency to market products on the claim that they will have slenderizing effects. Some of these products are definitely harmful. One of those which the Federal Trade Commission undertook to control was characterized by the Supreme Court as a dangerous product.

There can be no question about the necessity for the protection of public health by the extension of the provisions of this act to cover those articles.

Again, there are devices that are advertised, as the Secretary of Agriculture in his statement indicated to you, for heightening people; devices that are sold to make people taller; devices that are advertised to correct physiological or anatomical defects that may not in themselves be diseases, such as nose straighteners; most of them are pure frauds; many of them if used will produce physical harm, sometimes of an irreparable nature.

The next definition is that of cosmetics. Of course, this has no counterpart in the existing law. It may be of interest, however, to the committee to know that in the first drafts that were prepared of the existing act the term "cosmetics" was included. In the bill submitted originally by Dr. Wiley the definition of drugs included cosmetics. That was eliminated in the progress of that measure in Congress.

Senator COPELAND. Did the bill as introduced contain cosmetics?

Mr. CAMPBELL. There were several bills introduced, Senator, bills for the regulation of foods and drugs having made their appearance in Congress several years prior to 1906. I am not sure whether this definition of drugs to include cosmetics appeared in the first measure. Certainly it appeared in some of the later measures.

The remainder of this section is devoted to the definition of such terms as "person", "Secretary", "label", and "labeling"; the last is one to which I wish to direct your attention.

At the present time the law has control over those statements that are attached to or that accompany the package in the form of circulars. For purposes of the subsequent requirements of this bill these have been divided into two classes; first, "label" meaning the principal label or labels upon the immediate container of any food, drug, or cosmetic, and upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic. Then the term "labeling" is defined so as to include not only the label but all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug, or cosmetics. There is the definition of the term "advertisement" and, finally, the term "in package form" including wrapped meats enclosed in paper or other material as prepared by the manufacturers thereof for sale.

There is no attempt made to define the package form of food, drugs, or cosmetics. In the existing law there is a requirement made by the Gould amendment of that act that foods in package form bear a plain declaration of the net weight.

The interpretation of the term "in package form" was such that it did not include wrapped meat; and subsequently Congress passed an act, known as the Kenyon amendment, definitely and legally extending the terms of "in package form" to include meat products. Congress having expressed its purpose to have this included, the only reference in this section to definitions of "package form" is to assert that the requirement of Congress as previously expressed shall be carried in the pending bill.

Senator COPELAND. May I ask one question regarding line 13 where it speaks about graphic matter. That would cover the picture of some nice succulent peas in a can?

Mr. CAMPBELL. Exactly.

Senator COPELAND. Can you reach that obviously misleading practice under the present law; that is, in the definition of the term "labeling"?

Mr. CAMPBELL. We can because the term "misbranded" refers to designs and devices. So the reference to graphic matter in the bill is no addition to the present terms of the act, Senator.

Section 3 defines the adulteration of foods. It is the first of the several substantive provisions to appear. It declares a food to be adulterated if its use may be dangerous to health. That provision is new.

In the present act the statute declares food products which may contain added deleterious or poisonous ingredients to be adulterated, and then only, when they have been added in sufficient amount to render the foods possibly dangerous to health.

The purpose of this language in the bill is to proscribe the interstate shipment of food products that may be dangerous to health, whether the danger to health is normal in the food product or may be due to an added ingredient.

There is a practical necessity for that thing. Under the present law we are unable utterly to proceed against those products which may constitute a prejudice to health because of some natural ingredient which is deleterious. Certain beans, like Burma beans, that is, of the lima bean type, contain a glucoside which will yield prussic or hydrocyanic acid. A number of deaths have been recorded among consumers of such beans. As a matter of fact, we do not permit them to enter this country, but once in this country, and commingled with commerce, we cannot invoke the import sections of the act. There is no power to take them off the market. We encountered on one occasion that precise situation.

On the western coast certain mussels in their biological development at certain seasons of the year have been found to be definitely injurious. Under local regulations a ban has been placed throughout those seasons upon digging, marketing, and sale of these mussels. If they were to escape local officials, if such products were to go into interstate commerce, there would be no power under the terms of the present Federal law by which they could in any way be libeled. Obviously it is to the interest of consumers to protect them from such dangerous products, whether the dangerous ingredient is an added one or normal.

Senator COPELAND. Would that cover the possibility of the germs of botulism being in ripe olives?

Mr. CAMPBELL. Yes; it would cover that. Under this section of the bill, since ripe olives containing the botulinus germ are dangerous to health, they would be covered. We can, and do deal with the botulinus situation under the present terms of the law, however, on the ground that foods containing this organism are in part decomposed.

The next provision is, "If it bears or contains any poisonous or deleterious ingredient prohibited, or in excess of the limit of tolerance prescribed by regulations as hereinafter provided."

I think perhaps a better understanding of the measure, at least from a subject matter standpoint, can be acquired if we turn now to section 10 of the act to which this language refers and discuss it briefly. You will find that on page 14.

Senator COPELAND. This proposed legislation would cover spray residue for fruit?

Mr. CAMPBELL. Yes. Paragraph (a) of section 10 states that—

> If the Secretary finds that the presence of an added poison or added deleterious substance in or on food or cosmetics is or may be injurious to health, taking into account other ways in which the consumer or user may partake of or be exposed to the same or other poisonous or deleterious substances, then the Secretary shall by regulations promulgated after notice and hearing prohibit such added substance in or on food or cosmetics, or establish tolerances limiting the amount therein or thereon, to such extent as he may deem necessary to prevent such injury to health.

This is an extremely important, in fact, one of the most important provisions of this bill. It may be impossible to preclude absolutely poisonous ingredients from foods. Some of the deleterious ingredients with which we have to deal are to be found universally. But it is important that they not only be kept to such a low limit in each article of food in which they may be found that that article of food itself may not be dangerous to health, but important, furthermore, that the total intake of poisons by the consumer of foods from all sources be restricted to an amount which will not be dangerous to health.

Perhaps, with the development of the country, the extension of industrial activities, we can anticipate to some degree the more or less universal appearance of some of these poisons. Let me illustrate in a concrete way. One manufacturer of an article of food in which sugar was used in material quantities undertook control of his product by effecting a complete elimination of harmful ingredients. He found arsenic appearing in the article of food. He traced the ingredients of which that food product was prepared to their source in every instance in an attempt to determine the cause for the appearance of arsenic. One of the last ingredients to be investigated was sugar. He found to his surprise that the stock of sugar which he had on hand and from which this product was being prepared did contain arsenic. That is not a normal ingredient in sugar. But in the particular refinery where this stock had been prepared it was found that the sugar when stored in barrels and before those barrels were headed was placed on a floor of a room in which the windows were open, the smoke from a nearby smokestack entered the open windows and contaminated the sugar with arsenic.

I am referring to that merely to illustrate the circumstances under which added poisonous ingredients may make their appearance in food products, not as the result of careless operations in all instances

by manufacturers of such food, but despite precautions that they may take to effect absence of them.

There is a counterpart to this particular measure in that portion of the Food and Drugs Act to which I have referred once or twice already. Section 7, paragraph (5), declares that a food product will be held to be adulterated if it contains any added poisonous ingredient which may render the article injurious to health. It is under that section that one of our greatest activities under the Food and Drugs Act has been carried on. It is under that section that we are attempting to deal now with the spray-residue problem. We are spending on this project approximately one third of the appropriation for the enforcement of this law. There is no method by which many crops can be grown to maturity for marketing without the application of poisons to kill pests. If those poisons remain in sufficient quantity on the product at the time of harvest, of course they will be injurious to the consumer.

You know the extent to which this matter has been agitated; fruit and vegetable growers have followed the instructions issued to them by official agencies for the use of insecticides. It became the obligation of the same agencies then to advise the growers about methods by which this spray residue could be removed. Methods more or less satisfactory have been devised, and in the majority of cases, particularly the fruit products, the amount of residue encountered now is below the tolerance which has been determined as safe for consumption. But, Mr. Chairman, and this is another important argument for this particular paragraph, under the terms of the present law we are able to consider only a single commodity. If that single article of food does not contain poison in excess of the tolerance that has been determined as safe for consumption, it is not in violation of the present law. But suppose that article contains just a little less than the safe tolerance. Multiply that by the number of articles of food also containing traces of added poisons which constitute our daily diet, and you can get some conception of what the general intake of poisonous substances would be.

Now, while there is an economic need for the use of poisonous sprays, there is no justification at all for the appearance of these poisonous ingredients in a great many food products.

We are encountering the very same deleterious ingredients that are to be found on fruits and vegetables which are sprayed with insecticidal poisons in articles of food where the cause is entirely a matter of carelessness; a condition which can be definitely overcome if there is a serious attempt on the part of manufacturers of such foods to do so.

Under the terms of this bill the Secretary will be permitted to establish tolerances. There will be a definite recognition of the fact that at least for the time being and until, perhaps, the ideal spray has been found which will destroy pests and not be injurious to man and not damage foilage, we will have this spray residue question with us; but if there is a recognition of a definite tolerance in that case it does not follow that an equal amount of poison should be tolerated in other articles of food where there is no excuse whatever for it. But, in the face of the present limitations of the law we are permitted to deal with but one article of food at a time and are not permitted to consider various other sources of poison.

Senator COPELAND. What would be the method of determining the tolerance?

Mr. CAMPBELL. We would determine the tolerances under the provisions of this section exactly as we do the tolerances under the provisions of the existing law.

The Secretary convened in Washington the oustanding toxicologists of the country. There was no disposition to rely exclusively upon the conclusions of the scientific men in the Department able to speak intelligently about toxicological questions. It was an attempt by the Secretary to get an expression of the best scientific viewpoint from all sources. The people brought to Washington to give consideration to this question, realizing at the time its tremendous importance, both to the consumer and to the agriculturists of the country, were men who could speak with authority on it.

Senator COPELAND. Then it would not be merely an arbitrary establishment on the part of the Bureau of the degree of the tolerance?

Mr. CAMPBELL. Indeed no. Furthermore, the growers and others commercially interested would be heard.

Senator COPELAND. It would be done by scientific study and research?

Mr. CAMPBELL. Quite right, and I would like to say that if there were to be an arbitrary determination which was capricious, quite naturally it could be overturned by an appeal to the court.

Senator COPELAND Is such provision made in the bill? Is it clearly stated in the bill that there would be a possibility of such an appeal?

Mr. CAMPBELL. That nas not been definitely stated. That is not necessary. Such a court review can always be had, Senator. There is no question whatever but what the courts have the right to review every section of this law and every regulation promulgated by the Secretary under the law. It is expected that that will be done; and if the action of the administrative agency has been found to be arbitrary, unreasonable, capricious, and not predicated upon evidence and upon facts, there is no question but what the courts will not sustain it.

Turning again to this section for a moment, and illustrating the need for it, let me tell you that, in our experience in the enforcement of the law, we encounter frequently proposals by manufacturers to use harmful ingredients merely to improve the appearance of products. One proposal, to speak concretely, that came to us very recently, is the use of ethylene glycol, an antifreeze, in frozen eggs to give them that velvety texture characteristic of superior quality.

Another proposal was the use of antioxidizing agents for chewing gums to prevent it from aging, as occurs with automobile tires or other rubber products.

While there has been prevention by administrative discouragement, let me point out to you that, under the terms of this bill, there can be no prohibition of such practices unless it can be shown after the product enters interstate commerce that through such added deleterious ingredients the article may be dangerous to health. The Government is required to show that affirmatively in every case. It is difficult to present technical testimony to a jury of laymen. To deal with it adequately, this same technical testimony must be presented in every case where a contest develops.

We have been called upon to try one case after another at short intervals, where, in each, it was necessary to have an array of scientific witnesses. It is an extremely expensive procedure. Although the argument is weak, that this particular provision should be adopted in order to make possible more convenient and less expensive administration, I merely wish to point out to you that it is much more scientific and just, offers greater protection to the consumer, and more uniform control, to reach a determination on the basis of scientific opinion of what, generally, should be the limits of tolerance, and let that be the law applicable to these various products rather than to have the issue determined, as now, in each individual prosecution

Senator MCNARY. Mr. Campbell, you mean you want to change the rules now in force in the trial of cases, the taking of jurors from the body of the country and have a jury of scientific men; scientists, economists, and professors?

Mr. CAMPBELL. Not at all, Senator. We are proposing here, in this, and other sections of the act, to have authority conferred upon administrative officers to make certain findings of fact. That is true not only with this section but with the section that authorizes standards for food products. The regulations based on these findings of fact will carry the force and effect of law unless there shall have been shown an arbitrary or capricious or unreasonable attitude in determining them. When promulgated, they would be standards precisely like those we now have for the regulation of traffic in drugs.

There is a legislative standard for butter. It requires that butter contain not less than 80 percent of butter fat. To prosecute for violation of this standard the only requirement is to show by our witnesses that there is less than 80 percent of butter fat.

If this section of the bill were to be enacted there could be by executive action the establishment of legal tolerances for added deleterious ingredients.

The only appearance at court would be that of witnesses to show that the deleterious ingredient was present in an amount greater than permitted by the tolerance.

The CHAIRMAN. Is that other difference that the butterfat is actually established by the law?

Mr. CAMPBELL. Yes, sir.

The CHAIRMAN. Here the quantity of harmful substances would be left to regulation by the department?

Mr. CAMPBELL. That is right.

The CHAIRMAN. What would be the distinction other than that?

Mr. CAMPBELL. The point I am trying to make, Senator, is this: Congress has conferred upon administrative agencies repeatedly authority to make findings of fact to achieve a definite legislative intent. It has been repeatedly held by the courts that this was not an unconstitutional delegation of legislative power. A similar proposal is made in this case. I have no brief to hold for that procedure in lieu of a determination of specific tolerances by the Congress, and the very definite incorporation of them in the law, if Congress wishes to do it.

The CHAIRMAN. I assume that you desire, as pictured in this bill, that the department, through some methods they shall work out, shall establish these various tolerances and then if you have them disputed in court, there would be one determination that a certain amount of arsenic would be the limit that can be used in a foodstuff. And, then,

by that one decision, you would then establish that that was the legal limit of the use of arsenic; is that right?

Mr. CAMPBELL. That decision, if it supported the view of the Department, would be of value. It would not preclude the opportunity of any person to question the soundness, the sufficiency of evidence, or the arbitrary nature of the administrative determination at any subsequent time. There would be available always the opportunity to a defendant; first, to attack these tolerances as such, on the ground that they were not justified, that they were arbitrary and unreasonable; there would be that opportunity, then, in the second place, to make a defense at the time of the trial of any case that might be brought up.

The CHAIRMAN. I was quite clear about the example you gave about the butterfat. I got the impression in mind there would be some establishment of a standard as regards tolerances in reference to various poisons.

You could not establish that by act of Congress to really fix the tolerances that would be permitted?

Mr. CAMPBELL. Perhaps, but would it be practicable?

It would take an act of Congress of the sort that we are asking in this particular section to provide satisfactory control.

The CHAIRMAN. Then, where tolerances would be fixed by your scientific committee, they would also always be subject to attack in the courts?

Mr. CAMPBELL. Senator, we have tolerances now; merely administrative tolerances.

The soundness of those tolerances must be shown, the evidence on which they are predicated must be introduced in ample volume in connection with every trial that develops upon any product where this charge is involved.

What we are undertaking to do, for the benefit of the public generally, and, of course, to make the regulation of traffic containing added deleterious ingredients more effective for the protection of the public, is to establish definitely, upon scientific bases, what the amount of poisons safe for human consumption will be.

The Congress, itself, could pass a measure establishing such tolerances.

Repeatedly, in this law, we have gone on the assumption that the questions arising in the regulation of food and drug products and traffic therein are so complex and so shifting that they do not lend themselves effectively to rigid legislative expression.

Further, we have assumed that it would be in the interest of the public and in the interest of honest manufacturers, to make some provision, similar to that made in this section, for an administrative agency to be empowered on a fact finding basis to give expression to a legislative intent, rather than have Congress attempt to legislate in such detail.

The principle upon which that conclusion is based can be found in innumerable legislative acts.

Senator MCNARY. Mr. Campbell, in plain orchard English, you mean that anyone who is charged with disobedience of this section is a defendant, and must come in court and establish his innocence beyond a reasonable doubt?

In other words, he is presumed to be guilty, and must defend himself, beyond a reasonable doubt, upon that presumption, and contrary to the usual course of law?

Mr. CAMPBELL. Unquestionably, Senator, if it were to be shown in the case of a particular defendant that his product contains in excess of the tolerance, action would be brought in the nature of a violation, but he would have an opportunity to defend himself against it.

Senator MCNARY. If you have a roomful of experts and professors, that come to examine a certain product that is manufactured by a certain process, or in a certain way, and your professors agree that there has been a tolerance there that has not been satisfactory, the defendant, in order to come outside of the provisions of this bill must come in and plead his case and establish his innocence.

Mr. CAMPBELL. The defendant will be required to show that the opinion of this group of experts was unreasonable.

In the first place, the law itself proscribes the interstate shipment of any food product dangerous to health.

Senator MCNARY. Why do you change the general order of proof that has come down to us from the ages in the common law of the English, and in our statutes, that a man charged must defend himself, but first, it must be shown to the jury, by the system that you propose, that he shall be deemed guilty by the opinion as presented by an organization such as you describe, of experts and economists and professors, and against which he will have to defend himself?

Why do you not go along in the ordinary, common way, of first proving him guilty, and then letting him prove himself innocent?

Mr. CAMPBELL. One reason, which I tried to point out before——

Senator MCNARY. You tried to point it out, but I am just not converted on that particular point to that particular plan of changing the established way of handling court procedure and giving the individual an opportunity, under this bill, not to have the protection of the law.

Mr. CAMPBELL. I do not think that he is denied that, Senator.

Senator MCNARY. You just said he was.

Mr. CAMPBELL. I said that he had the right to come in and defend himself.

Senator MCNARY. If it were shown by these experts and talented men, in their opinoin, that this individual had violated this law, and they seize him, he must come in court and establish his innocence; is that not so?

Mr. CAMPBELL. I do not know of any place where we can find a clear knowledge of what the physiological effect of these deleterious ingredients will be, except the scientific experts, and that does not mean a cloistered group of individuals who do not know anything about marketing operations of food products, necessarily; but we must turn to the medical fraternity, the pharmacologists, and the toxicologists, for information on this.

Let me say that we are proceeding here, in this instance on the broad assumption that there will be a sympathetic consideration of any proposal that we advance to make foods safe for consumption.

We think, at the same time, that there should be a recognition of the amount of added deleterious ingredients that come from all sources.

Senator MCNARY. I am not disagreeing with that proposal. For the years that I was Secretary of Agriculture, I had jurisdiction over this Food and Drug Act. We always went along with this. I have always supported the legislation of the committee.

I am speaking of the humiliation and embarrassment you are placing on the man charged by your experts with a violation, because you say that he must come in and not receive the protection of the law that is accorded to every other individual, charged with a violation of our criminal laws.

The CHAIRMAN. Is there not another element? We have two bottles; one giving a false impression, and not containing the food element which it is represented to contain. If these contents will not do any harm, that is one situation. Here, as I understand the testimony, they are seeking, beyond peradventure of a doubt, to safeguard the public health, where the lives and welfare of the people, the physical welfare of the people, is directly associated with the product.

Senator MCNARY. This is no different from any other changes offered in our criminal procedure. That illustration used, I believe, proves that. For illustration, let us say that there will be some deception practiced by reason of a small amount of ingredient in one jar of fruit juices.

If these talented men should capture some of the fruit in this can of preserves on the store counter or shelf, they will then charge this individual with having violated the provisions of the law, and then he will have to take the stand and prove to the satisfaction of the jury that he is without the provisions of the Act. He wants to reverse the order of proof. I do not want to go into that any further now. We will discuss that at length in executive session.

The CHAIRMAN. Go ahead.

Mr. CAMPBELL. May I just present this thought, Senator McNary? We can deal, in every individual case, under the language of the present law, with the particular product and prevent its being marketed if it contains any added deleterious ingredients which may be likely to injure health. We can take care of that situation in each individual case; fruit in one instance, eggs in another, and any other article of food.

What I am concerned about is the general intake from all sources. If we can only prevent any one food commodity from containing added deleterious ingredients in excess of the amount that will be detrimental to health, and if the same condition is true with respect to every other commodity, you, then, can see what the total intake of deleterious ingredients will be from all sources.

If there could be a legislative expression of safe tolerances and of other matters where it has been proposed to designate the Secretary of Agriculture as a fact-finding agency for that purpose, as I said a moment ago, it will be quite satisfactory to every one in the Department of Agriculture, and to the public, too.

But, I am not aware of any plan by which a concrete legislative expression could be made that would undertake to establish limits for added dangerous ingredients in some commodities and to prohibit them altogether in others where it is recognized that there is no reason or justification for their appearance.

The CHAIRMAN. Would it not be possible to establish those tolerances as regards arsenic and lead, which are the main substances used; are they not?

Mr. CAMPBELL. Yes, sir.

The CHAIRMAN. Is there not enough testimony now on file, and expert knowledge, to determine the tolerances as regards those particular articles?

Mr. CAMPBELL. I think that could be done. Certainly, that is true with respect to arsenic.

But, Senator, there are new proposals arising every day for new types of insecticides. Manufacturers have actually put on the market mercurial insecticides. Selenium is one on the market now, in a commercial way. We recognize the importance of sprays, and recognize the need for these poisons for the purposes which I have indicated.

The effect of abolishing these insecticides and permitting the growth and ravages of these crop pests would, in all probability, prevent the production of a sufficient fruit and vegetable crop to meet the food demands of the country. We have no desire to bring about such a situation.

The CHAIRMAN. What do you mean by an insufficient crop, or by a short crop? Would that be one that falls below the requirements of the country for that particular crop?

Mr. CAMPBELL. Yes.

The CHAIRMAN. You mean that we would have to choose between prohibiting the use of sprays, with the consequent increase in the insects, so that the crop would be destroyed, and proper regulation by which the public health could be protected, and the crops, at the same time grown?

Mr. CAMPBELL. Yes.

The whole idea, as we understand it, is to permit, first, the production of these crops; second, to see that they are marketed in a manner that is safe for the consuming public. The public should not be injured by poisonous spray residues. At the same time, we can not ignore the economic situation, the practical problem with which the grower is faced, in resisting the attacks of these insects, which endanger his crops.

We propose this legislation with a full and complete understanding of the necessity for the protection of the public health not only but also of the protection of the economic interests of the growers.

The CHAIRMAN. As a matter of fact, are there a good many places in your Department where the question of added poisons would come into play?

I assume it was largely with reference to the spray residue that the chief menace existed.

Mr. CAMPBELL. Not at all.

This is the chief menace, of course. These sprays form a very large part of the group from which the added deleterious substances come. These particular products are those on which we have spent much time and money. They are not alone. There are a great many products in which added deleterious substances may be found. They are being discovered every day. We never know where we are going to find them. They may be found where least suspected, due, sometimes, to careless manufacturing operations, such as using lead manufacturing equipment, and such as the deliberate addition of ethylene glycol to frozen eggs, as mentioned a moment ago.

It seems to me that there is an opportunity, under the terms of this measure, for the protection of the consumer by the requirement

that, when they are unnecessary, added deleterious substances should be eliminated altogether. We recognize, at the same time, that tolerances must be established for fruit and vegetables, but should be restricted to amounts safe for consumption.

The CHAIRMAN. It occurs to me that ease of administration would be materially promoted if you have a small group of poisons now known to the Department as likely to be found in food—I am referring now to chemical poisons—that if you actually wrote into your bill the tolerances and quantities which would be permitted, you would have the same ease of administration that you have with regard to butter.

Mr. CAMPBELL. Quite right, if that could be done. Of course it would be the ideal and proper way, but I doubt whether it can be done. Shall I go ahead with section 4?

The CHAIRMAN. You may proceed.

Mr. CAMPBELL. On line 3, page 4, under item (3) of this subparagraph, the same language is used to define adulteration that is now employed in the present act.

Under item (4), you will find the new language. It is: "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth;"

Under the present law, the only action that can be taken to require the observance of sanitary precautions in the handling of food is to be found in section 7, paragraph 6, which deems a food product to be adulterated if it is filthy.

The CHAIRMAN. Would that cover rat dirt and the excreta of animals?

Mr. CAMPBELL. Yes; it would cover that and as a matter of fact, those instances where food had been prepared under objectionable and thoroughly insanitary conditions, even though you could not find, upon an objective examination of the sample, the evidence or definite proof of that filthy condition.

Let me illustrate: On the Eastern Shore of Maryland and Virginia, there is a concentrated industry engaged in the preparation of fresh crab meat. It is a favored article of food along the eastern coast, and also in certain other sections of the country, at certain times of the year.

In some places, it has been found that the conditions under which this perishable food product was prepared were such as to lend themselves to contamination of this food. Such contamination has manifested itself by outbreaks of illness in the principal consuming sections of the country.

Perhaps the very food that may have been responsible for the illness had been sampled and examined by the Department, but the limitations of bacteriological examination are such that affirmative evidence of the filthy condition could not have been obtained in all cases.

The only thing that is required here is that there be adopted a decent system of cleanliness in manufacture. Particularly is this essential in perishable foods of this type.

This is a requirement that is imposed by a great many of the States in one form or another. Those States which have adopted requirements, in some form, comparable or identical with the language suggested here, are Maine, Maryland, Mississippi, Nevada, New Hampshire, New York, Oregon, Pennsylvania, South Dakota, Texas, and Wisconsin.

If there is required to be maintained this standard of acceptable sanitation, in the production of food products for consumption in those States, and if there is no protection by means of a provision in the terms of a Federal law, and if there is a State which has no legal requirement for the observance of these sanitary conditions, it is utterly impossible for those States just enumerated to take any legal action for the protection of consumers in such States.

I do not imagine there will be any objection voiced to this item by anyone, Senator.

It is obviously an essential requirement.

Item 5 of that paragraph is the same as found in the present law.

Item 6 is a new one.

"If its container is composed of any poisonous or deleterious substance which may by contamination render the contents injurious to health."

This is not to be found in the present law, but need for it will be definitely recognized when I refer to the use of lead chests, or lead containers, for the packing of tea. It has been found that through the abrasion of the leaves the lead content of the container does become, in the course of time, and through extensive handling, more or less disseminated through the tea, throughout the package. It has been found in the brew made from such tea.

There are other packing methods that can be adopted that will avoid this objection.

The elimination of lead foil by the use of tin foil or of aluminum foil would do so. There is a definite remedy, and there is no definite hardship placed upon the manufacturers because of the variety of containers that exist today. The provision certainly is essential for the protection of the health of consumers.

In paragraph (b) of section 3, the first, the second, the third, and the fourth items are substantially as they are to be found now in the law.

In some instances these requirements have been made in modified form.

Paragraph (c). Confectionery. It retains the existing prohibition against the presence of alcohol. It also prohibits resinous glaze, or nonnutritive substances except coloring and flavoring—this is new.

That particular phrase "or nonnutritive substance" was intended to take care of the candy-carrying trinkets of the sort that have been in the recent past extremely popular. If you will notice, from the specimen of candy in this jar, the individual pieces of candy have been cut apart in order to let you see the location of the trinkets inside. Those that have not been cut contain these trinkets inside. You can see the different types of trinkets, themselves. There is no question about the risk to children in the consumption of this candy, not only because there is a likelihood of breaking teeth, but because of the possibility of swallowing the candy, and aspirating the trinket, and requiring a surgical operation of a serious character to remove it.

Here is an X-ray photograph showing that this is not merely an imaginative danger or a mere speculation as to possible victims of the consumption of this candy, but it shows the location in the trachea, of this metallic trinket.

Note, please, that this same item involves a specific prohibition against resinous glaze. A great deal of candy of certain types is found to be coated with this glaze. In a great many instances it is nothing more or less than shellac.

Under the terms of the present law we cannot take action against it. Under the terms of the present law we can take no action against that specimen containing trinkets.

We brought prosecutions but the court held that that practice was not violative of the present law.

Stroud Jordan, in his Confectionery Standards, states:

> Glaze of any kind is not essential if the products are handled properly. Resinous glazes have no place in confectionery. They can only be classed as unnecessary adulterants.

There is one provision of that paragraph, Mr. Chairman, that we recognize would work a hardship, as it stands now. This was not apparent to us at the time the bill was drafted. There would be, perhaps, a complete prohibition against chewing gum, the chicle in it being a nonnutritive substance.

We would suggest that the wording be modified, and that after the phrase "or nonnutritive substance except coloring and flavoring," the following words be added "and masticatory substances used in chewing gum."

The CHAIRMAN. You desire to add these words at the end of the line "and masticatory substances used in chewing gum"?

Mr. CAMPBELL. Yes, sir.

Paragraph (d) of this act makes it an offense to use a coal-tar color other than one from a batch that has been certified by the Secretary in accordance with regulations as hereinafter provided.

In section 10, to which we referred, on page 14, you will find, in the second paragraph of that section, line 8, page 15, that the Secretary is authorized to make regulations after notice and hearing, for the certification of coal-tar colors which he finds to be harmless for use in food.

The CHAIRMAN. That is not in the law now?

Mr. CAMPBELL. That is not in the law now.

The CHAIRMAN. It is there by regulation.

Mr. CAMPBELL. By regulation we have actually done that. After the existing law became effective the then Bureau of Chemistry, in recognition of the impurities to be extensively found in a great many coal-tar colors and the poisonous character of some of the colors themselves, issued regulations designed to assure the manufacturers and other purchasers that the colors used by them would be nontoxic and free from deleterious ingredients. These regulations established the practice of examining and certifying the purity and safety of coal-tar colors as a method for the protection of the public.

It is desirable that it be continued. In this language we are asking for legislative confirmation of a practice which has existed since 1907.

The CHAIRMAN. Has that been disputed particularly by the trade—those regulations?

Mr. CAMPBELL. There were some objections in the early days, of course; but it has not, in recent years, been disputed or protested by manufacturers of colors themselves.

The CHAIRMAN. I suppose that is due to the fact there is wider knowledge of the real menace of the use of these products otherwise?

Mr. CAMPBELL. Yes.

The next is section 4, the adulteration of drugs.

Paragraph (a) is new. There is no provision in the act at the present time to suppress the marketing of dangerous drug products. The necessity for that is very distinctly and definitely illustrated, Mr. Chairman, in the consequences from the consumption of Radithor which, as the label states, is a radium-containing water.

The product has resulted in death, despite repeated warnings by the Department. There is no provision in the law that will enable us to remove it from the market. It has been claimed that this provision may affect all types of medicine because all medicines which are potent are capable of producing injury, but this particular paragraph, as you will note, is one that condemns such drug products if dangerous to health under the conditions of use prescribed on the labeling thereof.

And, in a later section it will be made a requirement that the conditions of use shall be stated on the container of the drug.

I wish to rush along with this as rapidly as possible. If there is any question you care to ask, I shall be glad in that event to discuss that item more fully with you. I wish to give concrete reasons for some of these provisions.

Provision (b) deals with official products, that is, those recognized by the United States Pharmacopoeia or National Formulary.

The CHAIRMAN. Is there anything new in regard to that?

Mr. CAMPBELL. The phrase "or simulates" in line 5, on page 5, is new. The other language is substantially the same as the present law down to line 9 "and when it fails to meet the definition, formula, and description set forth therein." That is new.

The present law requires official drugs to comply only with the standards of strength, quality, and purity as determined by the tests prescribed by the United States Pharmacopoeia and National Formulary.

The CHAIRMAN. Let me ask you about line 15. Do you now have that arrangement at present, that power given to the Secretary?

Mr. CAMPBELL. No. All of this language from line 13 down to and including "standards" is new language.

The purpose of that is to make it possible for the Secretary of Agriculture, in cases of emergency which will arise from time to time, to provide methods for the determination of the standards of quality, strength, and purity of drug products which may supplement those already found in these authorities. Its only purpose is to maintain the integrity of the official standards.

The CHAIRMAN. I assume you are to have some support of scientific assistance there that you spoke of, professional assistance to help you in such a case?

Mr. CAMPBELL. Yes, there is no question about that. There is no question but what some of the methods from time to time become obsolete. The United States Pharmacopoeia Association meets once in 10 years. The Pharmacopoeia is issued once in every 10 years. Under present circumstances the revision committee has been empowered by that organization to effect ad interim revisions. If that authority were revoked and the Pharmacopoeial method were found insufficient to establish the identity, purity, quality or strength of a

drug or drug product, there could be no relief until the Pharmacopoeial Association met again.

The CHAIRMAN. I assume you would not use that system provided the United States Pharmacopoeia Association permitted the committee to act, ad interim; you would have no occasion to have it?

Mr. CAMPBELL. I doubt whether it will ever be found necessary to invoke this authority at any time. As we find new methods that reflect, more accurately, the character of the product, our purpose would be to report them to the revision committee and expect that modification of the official test would be made in the conventional way.

In other words, as we find new methods that reflect with greater accuracy the exact characteristics of some product it would be our idea to report them immediately to the revision committee, and we would expect an ad-interim modification to be made promptly and in the conventional way.

The CHAIRMAN. The rest of the subsection is the same?

Mr. CAMPBELL. In line 20 it is different.

In line 22, the word "differ" is used.

At the present time a product, sold under a pharmacopoeial name, which declares its own standard of strength, quality, or purity meets the requirements of the law, even though its label does not indicate wherein it differs from the United States Pharmacopoeia.

The purpose of the wording used there is to make it possible for a buyer to know how the product differs from the United States Pharmacopoeia standard without having to refer to the official book to ascertain that information.

Paragraph C is substantially what is in the act at the present time, with the exception that in line 5, the words, "and its identity or strength differs from", involve a new requirement.

At the present time the law states that if a drug product falls *below* its own declared standard of strength, it shall be adulterated.

Perhaps the most serious danger to purchasers of drugs is to be found in those drug products which are of excessive potency rather than those that are below the declared standard of strength. If such products are relied upon by physicians and exceed the expected standard of strength, and the physician is using them under the impression that they are of the standard of strength set forth, you can see what the result might be in a case of serious illness and delicacy.

This language here reads, "if it is not subject to the provisions of paragraph B of this section, and its identity or strength differs from, or its purity or quality falls below, that which it purports or is represented to possess." In the present law it reads, "if its strength or purity fall below the professed standard of quality under which it is sold."

So, it will be observed that the language is the same in substance, with the addition which I stated.

Paragraph D is new, but its purpose is merely to preserve or guarantee the integrity of the product.

The next is cosmetics. This is, of course, without counterpart in the existing law. I do not know much about conditions to be found in the general run of cosmetics today. The effects of the use of certain articles have come to our attention in some few instances where we have made investigations of a superficial nature.

I do not think it will be denied by cosmetic manufacturers that there is a need for regulation of this industry. Some very definitely tragic occurrences have been recorded.

Here is a product that is off the market now. It is a depilatory and contains thallium acetate. It has been responsible for injuries of an irreparable sort. Notwithstanding that fact, it was advertised as safe for use.

Here is another article by the name of "Lash-Lure." It is to be used in the treatment of eyelashes. This is a photograph of an individual before using it. This is a photograph of the same individual a few days—only a few days—after using it, showing the effect of this cosmetic.

Here is a placard advertising the product that I have just pointed out to you, which we obtained from a local store in Washington.

It is actually on the market at the present time.

I have nothing more to say about section 5.

The CHAIRMAN. Let me ask one question.

Line 14 says, "if it is or may be injurious to the user."

How would you determine that; by a scientific and clinical test?

Mr. CAMPBELL. It would be determined in the same way, Senator, that the identical question is now determined with respect to poisons in foods.

The toxicity of the product would be appraised by taking into account the work done by anyone in the field, not necessarily in our organization, but a general survey of the entire situation.

In other words, it would contemplate the utilization of all available scientific information which we could secure upon the subject.

The CHAIRMAN. Would there be any objection to changing that to read, "If it is or has been found by scientific or clinical tests to be injurious to users"?

Mr. CAMPBELL. I am not sure that I am aware of your point.

I do not know in what respect your definition differs from the one here.

The CHAIRMAN. To be certain that it is not an arbitrary decision on the part of the department. I do not press the matter at all.

Mr. CAMPBELL. Do you wish to discuss that now?

The CHAIRMAN. No. Go ahead.

Mr. CAMPBELL. The following section defines misbranding.

The first portion relates to general misbranding.

Paragraph A reads, "if its labeling is in any particular false, or by ambiquity or inference creates a misleading impression regarding any food, drug, or cosmetic."

Senator MCNARY. Is that new?

Mr. CAMPBELL. Yes.

That is new language. It is the requirement in the act now, but new language to inlude cosmetics.

Senator MCNARY. Then it really would be new language.

Mr. CAMPBELL. To that extent; yes, it would be new language.

In view of the fact that there has been so much comment about that paragraph, the alleged harshness of its terms, I wish to make further reference to it.

Section 8, on page 17, of the Food and Drugs Act reads——

The CHAIRMAN. What section do you have reference to?

Mr. CAMPBELL. Section 8, on page 17, if you have the same copy that I have.

That the term "misbranded" as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device, regarding such article, or the ingredients, or substances contianed therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured of produced.

The language that we have employed in paragraph A of section 6 of the present bill requires nothing more than the existing language does.

In the Supreme Court's interpretation of the existing language occurs this statement:

The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity as well as from statements which are false.

We have frequently encountered what we considered to be unquestionably misleading statements appearing on labels. This even though the individual sentences comprising that statement might be true and could not be refuted. The inference was undoubtedly of a character to deceive and mislead the purchaser.

Our thought was that misunderstanding on the part of manufacturers would be overcome by giving them adequate notice of their obligation and of their responsibility by saying quite definitely. "If this labeling is in any particular false, or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetic."

The CHAIRMAN. Would the thought you have in mind be made if it were to read, "If this labeling is in any particular false or if unsupported and unscientific claims are advanced"?

Mr. CAMPBELL. I am sorry I do not understand your point.

The CHAIRMAN. Or if unsupported or unscientific claims are advanced.

Mr. CAMPBELL. Yes; if we were making a prohibition against a certain type of misleading statements. But that would not be sufficiently inclusive, do you think, Senator, to cover the category of misleading statements which are made.

The CHAIRMAN. The objection I have to this subsection is its very ambiguity.

Mr. CAMPBELL. That it is ambiguous?

"If this labeling is in any particular false"? That is clear to me, and I am afraid I do not understand your point.

The CHAIRMAN. That is what I had reference to.

Mr. CAMPBELL. Why not write it in the form we propose?

If it creates a misleading impression, it is immaterial whether it is by way of ambiguity or inference. The object of this language is to prevent that.

The Supreme Court has taken into consideration that this is a statute for the consumer, and that the labels on the product must be free from any false, ambiguous, and misleading statement, even where that misleading statement is created by truthful declarations.

Let me point out this to you; let me call your attention to this sheet here.

There is a full page advertising statement—a full page advertisement stating the fact that colds are injurious; in other words, stating that you should avoid colds if you would guard against tuberculosis. The word "tuberculosis" is in big letters at the top.

If you will read all of that statement, I doubt whether you will find any single sentence to which you can take exception, but unquestionably the general inference on the part of the individual who reads it, and I submit to you that that would be a normal and justified conclusion, is that the article advertised is of some value in the treatment of tuberculosis.

The CHAIRMAN. Let me ask if there is any particular change between the present language and the language you have here, in any great particularity?

In other words, if it is at the present time a violation, if this label has anything of if that creates a misleading impression.

Mr. CAMPBELL. That is the requirement of the present law.

The CHAIRMAN. Do you have a court decision sustaining you on that?

Mr. CAMPBELL. Yes.

I will read it.

"Which shall be false or misleading in any particular."

That is the language of the present act.

There can be no objection to the use of that language in this bill if you prefer it.

I have told you what the Supreme Court said in the interpretation of that language. It condemned labels creating misleading impressions, even those impressions that might result from inferences or ambiguity.

Our purpose in stating that fact specifically in the language was to make the manufacturer of foods, drugs, and cosmetic products aware of his own responsibility.

Our thought was that, with the knowledge of the requirements of this act, he would violate the law less frequently than otherwise.

The CHAIRMAN. I presume the Department is not proud of the authorship here, particularly?

Mr. CAMPBELL. Oh, no.

The CHAIRMAN. Then let the record show the reference to the Supreme Court decision.

Mr. CAMPBELL. I read from United States Reports, volume 265, at page 438.

Paragraph B. "If in package form it fails to bear a label containing: (1) the name and place of business of the manufacturer, packer, seller, or distributor."

That is new. That paragraph was put in at the request of State officials. When they have occasion to investigate products sold by peddlers in their jurisdiction, this information is valuable.

(2) An accurate statement of the contents in such terms of weight, measure, or numerical count as may be prescribed by regulations of the secretary.

The CHAIRMAN. That is new?

Mr. CAMPBELL. That is, at the present time, the law as it applies to food. One (1) is new; (2) is the law, substantially as it is now.

The CHAIRMAN. How does it differ from the present law? You say it is substantially the same?

Mr. CAMPBELL. This is the Gould amendment of the act. There is a proviso—from line 10 and including line 19—which is new language.

The CHAIRMAN. From line 10 to line 19 is new language?

Mr. CAMPBELL. Yes.

That gives the Secretary of Agriculture power to make exemptions where canned food products are put up at one of several factories, and brought to some central point where they are labeled before being placed upon the market.

As a matter of fact, that has been done. That is what has been done administratively, by the secretaries in the past, and this is asked, simply, as legislative confirmation of such action.

The CHAIRMAN. Has that anything to do with apples?

Mr. CAMPBELL. No.

The CHAIRMAN. I was not purely facetious in what I have said.

It has been the fear of some apple growers that this food and drug bill would take over the regulation of the contents of baskets or packages of fruit.

Mr. CAMPBELL. I think that question will present itself in a following section.

I do not think there is any objection by any of the industries to this portion that we are discussing now. This is the entire paragraph B. Shall we pass on?

The CHAIRMAN. Yes.

Mr. CAMPBELL. Paragraph C. The purpose of that is obvious. That is new. Under the net-weight requirements at the present time, it is provided that the quantity of contents must be plainly and conspicuously marked or declared.

That has been omitted from the above portion and the general requirement included in paragraph C, for prominent and legible statements of all label declarations required by the bill.

The next is "misbranding of food." A food shall be deemed to be misbranded if its container is so made, formed, or filled as to mislead the purchaser, or its contents fall below the standard of fill prescribed by regulations as hereinafter provided.

This item is nothing more or less , in different language, than the old slack-pack measure that passed the House on 3 or 4 different occasions but never has become law.

Here are a number of samples that illustrate the necessity for that particular paragraph.

The CHAIRMAN. I did not get much encouragement from the Senate when I had that bill in.

Mr. CAMPBELL. I hope you will when it appears in this bill. Certainly it is needed. This package of spice, black pepper, is a little more than one half full. The content of it can be seen as indicated by the line on the package.

The consumer would assume that it is entirely full and has a right to that assumption.

This package of cheese has a false bottom. The way to detect the extent of deception created by this extract bottle is to turn it up and look through the bottom.

Shall I pass on to the next section?

The CHAIRMAN. Yes.

Mr. CAMPBELL. Here is an interesting form of deception, Mr. Chairman, that should be seen in connection with this provision.

These are specimens of plain noodles, both without eggs. But one is packed in yellow cellophane to create the impression that it is an egg noodle.

Before I leave the paragraph, let me present an advertisement, Mr. Chairman, which is illustrative of the extent to which manufacturers are selling containers on the ground that they will create a false impression among consumers.

Paragraph B——

The CHAIRMAN. I read here, "You need not be a magician to make your eggs be the same size. Only an expert buyer, after careful study, could detect any difference in size."

This is advertising to a firm selling eggs?

Mr. CAMPBELL. The firm is putting out a box to make one egg look like the others in size. It will make them all look the same size.

Paragraph B and paragraph C are practically those that are now in the act.

The CHAIRMAN. B and C?

Mr. CAMPBELL. Yes. B and C.

The CHAIRMAN. Proceed.

Mr. CAMPBELL. We come now, Mr. Chairman, to paragraphs D and E.

The CHAIRMAN. They are new?

Mr. CAMPBELL. Yes. They are new.

Section 7, paragraph D——

The CHAIRMAN. That is on page 8?

Mr. CAMPBELL. Yes.

Paragraphs D and E, line 14:

> If it purports to be or is represented as a food for which a definition of identity has been prescribed by regulations as hereinafter provided.

Turning to section 11, because I think that would be the orderly way to consider this—that is on page 15—you will see that the Secretary is authorized to formulate and promulgate definitions of identity and standards of quality and fill of container for any food.

This is, to my mind, one of the most important provisions of the act.

The CHAIRMAN. That is here?

Mr. CAMPBELL. Yes.

Certainly, from an economic standpoint, it is the most important.

There are no legal standards now, by which there could be a regulation of food products. There are legal standards for drug products; the Pharmacopoeia, and the National Formulary are the legal standards for the regulation of the traffic in drugs.

This particular provision is one that has been recommended by the Department of Agriculture for the last 20 years, to my personal knowledge.

It is a provision that was recommended by Dr. Wiley in the original bill. It has been considered by Congress from time to time.

You introduced, yourself, Mr. Chairman, in the last Congress a bill to make provision for the administrative determination of legal food standards.

The procedure which we must follow now, is that of showing that trade custom, or household understanding has fixed the composition of food products and determined what they must be.

Paragraphs 1, 2, and 3, of section 7 of the existing law connote standards.

The language employed in the original law is:

> In the case of food, first, if any substance has been mixed or packed with it so as to reduce or lower or injuriously affect its quality or strength; second, if any substance has been substituted wholly or in part for the article; third, if any valuable constituent of the article has been wholly or in part abstracted.

How are you to determine when the standard of a product has been lowered? When some valuable constituent has been removed; or when some ingredient has been substituted, unless you proceed from a definite conception of a standard?

In the enforcement of this law now we are required to go into court and show by testimony of manufacturers, and the testimony of housewives, what that standard is.

You can easily appreciate the fact that the standard set up in such circumstances is not an exact standard. Manufacturing practices and consumer conception of standards of identity vary. This variation will involve a spread of from 5 percent to 10 percent or more.

We are now formulating and publishing administrative standards; as a matter of fact, that was done long before the passage of the present law. They have no legal status under the Federal laws.

The appropriation bill of 1902, up to and including 1906, carried items covering the expenses of the operations of a standards committee.

The issuance of administrative standards by a committee was renewed by us after a lapse of several years, for the very definite purpose of influencing manufacturing practices. We understand that such advisory expressions can do much to establish a uniform standard in the preparation of food products. Further we prepare these standards to meet the needs of some 20 States that have passed laws making these advisory standards of the Department of Agriculture legal in those States.

The CHAIRMAN. In this section 11, did my bill have practically this same requirement?

Mr. CAMPBELL. I think your bill indicated in more particularity what the committee should be and how it should function.

The CHAIRMAN. That is to say, my bill was a little more specific as to how these standards should be fixed?

Mr. CAMPBELL. Yes.

The CHAIRMAN. As a matter of fact, under this provision, as it is included here, how would the department fix the standards?

Mr. CAMPBELL. The Department would proceed in substantially the same way that it does now in the determination of these administrative standards.

There is a committee that is composed of departmental and State officials, and representatives from scientific associations.

There is an appearance before this committee, at periodic hearings, at which time we take up certain food products, the nature of which has been announced specifically, in advance, to permit manufacturers and others to discuss them.

Unfortunately, there has been no general participation on the part of the public, in spite of the fact that we have made these hearings known to the public, and have invited the public to attend.

At that time, there is an attempt by the committee to canvass the expectation of the buyer of the product and the difficulties involved in the preparation of it so as to meet that conception. The standard

authorized by this bill would not be set up on an arbitrary basis by someone in the Department, but on facts developed through the employment of groups of competent people, in the same way that the present standards have been arrived at. The standards committee would operate in the same way that the present administrative standards committee functions. As a matter of fact if this bill becomes law, it is my conception that the existing food standards established for administrative purposes would be adopted substantially as they are now.

The CHAIRMAN. I assume there would be first a notice of a public meeting, and there would be submitted to this group of experts, to this scientific body, provided for in some way, and after 30 days or some other time, a promulgation by the secretary of the standard so set up; that would become the arrangement. Would that be subject to appeal to the courts?

Mr. CAMPBELL. Yes. Any action we would take would be subject to court review.

Senator MCNARY. Does this general statute provide for any right of appeal from the Food and Drugs Act?

Mr. CAMPBELL. No; possibly the Code provides that.

Senator MCNARY. The right of appeal is not a common law right but must be specifically set forth.

Mr. CAMPBELL. There could be no objection to that being put in. It would, however, be necessary to establish a special court for the purpose since the establishment of a standard is a quasi-legislative and not a quasi-judicial act.

The CHAIRMAN. If the committee decides that there should be a right of appeal provided, the Department would not object?

Mr. CAMPBELL. Not at all. The Department is anxious to have provided some legislation which would permit administrative functioning for the protection of the public. This is now impossible because of the lack of legal standards, definite tolerances, and other features covered in this bill.

Turning back to page 8, may I say that this is an extremely important provision, not only from the standpoint of the establishment of identity standards as prescribed in D, but also the standards of quality provided for in (e). There has been more public interest in that paragraph and in its companion section in the misbranding portion of the act than in any other provision of this bill. The housewife is giving more consideration to questions of dietetics and home economics than ever before. Under the present law it is impossible to require labeling of an affirmative character regarding the composition or quality of food products. There is more and more a demand for that type of information. I was agreeable surprised when my attention was called a few days ago to the fact that this same provision was recommended also by Dr. Wiley in the measures that were considered prior to 1906.

Senator MCNARY. Was not that same recommendation made later on?

Mr. CAMPBELL. Yes. For standards and definitions, yes. This bill provides for definitions of identity, and standards of quality or grades. This section divides itself into grades and into standards of identity.

So far as E is concerned, this is actually being put into effect now, Mr. Chairman, by the Department of Agriculture, under an item in the appropriation bill, with reference to perishable farm products. What we are asking is legislation to extend the standard making authority to take care of the consumer interest in fabricated products as well as perishable farm products which are now being taken care of, as I said, through the grading operations of such products. We desire to extend this, from the standpoint of consumer interest, to fabricated products to which the items in the appropriation bill do not apply.

The CHAIRMAN. Is subsection F practically the same as the present law?

Mr. CAMPBELL. No; it is new, entirely.

The CHAIRMAN. Have you reached it now?

Mr. CAMPBELL. Yes. That is the section that requires a declaration of ingredients in food products in the order of their predominance by weight. It is to give to the consumer information that he cannot get at the present time. Let me tell you that more than a year ago, in order to counteract some of the vicious advertising practices that prevailed, the Department, at the invitation of the broadcasting companies went on the air with a series of broadcasts on the subject of "Read the Label." The reaction was instantaneous and extensive. But, in reading the labels, under the requirements of the present law, it was impossible for consumers to acquire much, if any, information. The only thing sought here is to require the manufacturer to give consumers the information necessary to make in intelligent purchase. This idea is not something new. Most of the States require such information to be placed on packages of feed for livestock. It seems to me with that interest which is being manifested in nutritional questions, the housewife is entitled to comparable information when it comes to the selection of food for her family.

The CHAIRMAN. Would it be required in a case of self-rising flour that there should be a declaration on the label of the flour as to the soda and the other contents of the flour, whatever those articles might be? Is that correct?

Mr. CAMPBELL. Yes; if it is an article or a product for which no definition or standard has been declared. What this paragraph does is to subject food products to the same supervision that drug products have.

The CHAIRMAN. That is to say, to use my same example, if you had established a standard of self-rising flour, there would be no occasion to put it on the label?

Mr. CAMPBELL. Yes. We have a number of exhibits here. I regret to take up so much time because I know how anxious you are to expedite this hearing, but I think I have here something that should be brought to your attention, Mr. Chairman. These are samples of a mixture of chicken and noodles. Notice the variation in the amount of the meat, the expensive part of it. You see it ranges from 9 percent to 15⅝ percent.

The CHAIRMAN. That is the percentage of meat?

Mr. CAMPBELL. Yes. You can see what this means to the consumer from the economic standpoint and also to the manufacturer who wants to maintain a definite standard. This shows exactly what competitive pressure will cause manufacturers to do. There

is no way by which we can require a definite standard now. There is no way by which the buyer can purchase understandingly or intelligently in the absence of informative labels. In the event that standards were promulgated for articles of this sort, they would be required to comply with such standards. Otherwise they would fall squarely within the provisions of paragraph (f). Notice the continuing portion of paragraph (f) which says that the Secretary is authorized to prescribe by regulations, requirements for such further information on the label thereof as he may deem necessary to protect the public from deception. The Secretary would be authorized to require manufacturers to disclose the percentage of meat or to give to the buyer that information in some other form.

That particular authorization to the Secretary is extremely important in more than just matters of economy. For instance, we know that tomato juice has been popularized because of its vitamin content. It so happens that it contains one of the very important vitamins, but one that is easily destroyed. Suppose a manufacturer were to prepare a product in which tomato juice is an ingredient, and in my selective purchasing I buy it because of that fact. If it had been found that the vitamin content of that tomato juice had been destroyed by processing operations it would be extremely important for my protection that some further information be given than that tomato juice is one of the ingredients.

The CHAIRMAN. Is there anything unusual in the language contained here that the Secretary is authorized to prescribe by regulation? Is this quite a common thing in the practice of the Department?

Mr. CAMPBELL. Under certain statutes it is not only a common practice in this Department but in other departments.

The CHAIRMAN. Proceed.

Mr. CAMPBELL. We now come to the misbranding of drugs. Paragraph 8 (a) (1) states that a drug is misbranded if its labeling bears the name of any disease for which the drug is not a specific cure but is a palliative, and fails to bear in juxtaposition with such name and in letters of the same size and prominence a statement that the drug is not a cure for such disease; or if its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.

I have read items (1) and (2). The particular significance here is in the word "cure." The form of statement is not prescribed. It may be expressed properly in any language which conveys the idea.

Senator MCNARY. That is not in the present law?

Mr. CAMPBELL. That is entirely new.

The CHAIRMAN. The whole section is new?

Mr. CAMPBELL. Not the entire section, but this paragraph of it. This is new. That entire paragraph (a) is new.

Senator MCNARY. Who would decide whether the particular drug is a specific or cure or palliative?

Mr. CAMPBELL. The court.

Senator MCNARY. This goes to court?

Mr. CAMPBELL. Yes; everything we do will go to court.

Senator MCNARY. This is very satisfying. Is it a very difficult matter for the medical experts to determine whether a drug is a cure or not?

Mr. CAMPBELL. No.

The CHAIRMAN. It is the requirement for an agreement of medical opinion. Do you regard that as possible?

Mr. CAMPBELL. Generally, yes. I am dealing with the first paragraph, I have not reached that portion of it to which you refer, Mr. Chairman. There are only a few specifics, but the public does not know that. The medical fraternity knows it and most manufacturers of medicines know it. The public, by the character of labels which prevailed prior to 1906, and the nature of advertising that has been extensively used since that time, has been led to believe that almost any concoction which manufacturers produce may be utilized to cure some disease. Where diseases are mentioned on labels the public thinks of the medicine usually in terms of a cure. Contrary to what has been asserted, in this paragraph we are not advancing the cause of the medical practitioners.

Senator MCNARY. I am not quarreling with you on that. This may have an angelical form and be a very angelical statement, but if you go into the drug store and buy a bottle of medicine that represents itself to be effective for a certain disease, who is to determine as to whether it would be a cure or a palliative? There is the difficulty I would experience in getting this medicine, in going into a drug store and purchasing a bottle of medicine.

Mr. CAMPBELL. I do not think that would be a difficulty.

Senator MCNARY. I might find it as a cure, and a member of my family might find it as a palliative, and someone else it would not do any good at all. I confess I am perplexed about that. Who would decide whether it was a cure?

Mr. CAMPBELL. If the manufacturers stated on the label that it was a cure for malaria and it did contain the amount of quinine and directions for the proper use of that specific, there could be no quarrel with it. On the other hand, if the package contained only those ingredients which would merely give relief from pain, and contained nothing really curative; if it contained substances used by the physicians for this purpose, or products employed in the home as pain relievers, and the label gave information as to its very definite pain-relieving value, there would be no objection. If it is not a cure of any disease but does contain the drugs which are recognized as being palliatives, it should be labeled as a palliative. The specifics are few and well known.

Senator MCNARY. Who is going to make for me decision as to the effectiveness of various drugs that I might take?

The CHAIRMAN. I think you have got to take that section along with the second subsection. It seems to me that you have to consider this under subsection (a) to answer what the Senator says.

Mr. CAMPBELL. This paragraph does not require, in this language, that the product be labeled a "palliative"; it does not require that it be labeled "Not a cure." The paragraph says in effect this: In those diseases such as influenza—and I think that medical science will admit that there is no specific cure for it; I think the chairman will bear me out that—the most the medical fraternity can do in influenza is to give you medicines which will relieve the distress until the disease has run its course. They give you palliatives, anodynes to ease the pain or discomfort while the disease runs its course.

Senator MCNARY. What was that?

Mr. CAMPBELL. I was saying that in diseases such as influenza, medical science knows nothing of a specific cure, and I think the chairman will support me in the statement that the medical fraternity knows of nothing that will prevent or cure this disease. The most that the medical fraternity can do is to let the disease run its course, and to give you medicines which will operate as anodynes until the disease has run its course.

The CHAIRMAN. I think that is a fair statement of facts.

Mr. CAMPBELL. Under such circumstances you should not be sold a remedy labeled as a cure for that disease unless it is a cure for that disease. You have the right to buy it intelligently. You should have the right to buy it with full knowledge of the fact that it will not operate as a cure if it is merely palliative. This particular paragraph proposes such a requirement. I might say that this particular paragraph, perhaps with the one relating to advertising, has been responsible for most of the widespread protests against this bill. It has developed the most bitter expressions of opposition. It is the opposition of those manufacturers who for years have made a rich living by preying upon the deluded public, whom they have deceived and defrauded from time immemorial. By playing upon their fears and superstitions, they have prepared and sold to the sick so-called medicines which are of little or no value in the treatment of diseases for which they are recommended. It is this group of manufacturers that have objected so strenuously to this part of the bill. It only provides for slight information. Manufacturers must make some label statement which will prevent the purchaser, the prospective buyer, from believing it to be a cure when it is only a palliative. That is about all this paragraph will do.

The CHAIRMAN. As a matter of fact, is that not the practice of the department now?

Mr. CAMPBELL. At the present time if a statement is made or the label of a medicine for the treatment of various diseases, and the medicine itself is of no value in the treatment of these diseases, and it can be shown that the manufacturer of the product knew that it had no value in the treatment of these diseases its shipment in interstate commerce would be a violation of the law; but proof of all these things is absolutely required in our testimony. What we are anxious to do in the protection of the public is to remove certain of the existing restrictive provisions and thus make possible better control of this situation. The language in the succeeding item (2) makes it unnecessary to show that the manufacturer knew the limitations of his product. It would no longer make ignorance a defense.

Senator MCNARY. You have made a very clear explanation and it may be a very good provision, but in the case of a difference of opinion among medical experts as to whether the medicine is a cure or a palliative, you go to the court for a final decision?

Mr. CAMPBELL. Yes. If there is a difference of medical opinion we would not go to court, because in order for the Department to take action, under the terms of this language, there must be shown; first, an agreement of medical opinion; and, second, that the claims made are contrary to it.

The CHAIRMAN. I think in your later section on page 13 you have made a list of those diseases?

Mr. CAMPBELL. Those are incurable diseases.

The CHAIRMAN. You come now to no. 2.

Mr. CAMPBELL. Let me point out to you what the effect of the entire paragraph (a) is. It gives to the consumer but slight protection. I am trying to show how that is. That language declares a drug shall be deemed to be misbranded, "if its labeling bears the name of any disease for which the drug is not a specific cure but is a palliative, and fails to bear in juxtaposition with such name and in letters of the same size and prominence a statement that the drug is not a cure for such disease; or if its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion."

I am not discussing further the terms "ambiguity" or "inference." I think we have gone into that sufficiently. You will notice that the item goes further; it requires that the remedial claims be not contrary to the general agreement of medical opinion.

Senator MCNARY. How is that competent? How is that general agreement of medical opinion obtained?

Mr. CAMPBELL. That can be obtained very easily. We obtain it in this fashion now; when we consider products whose labeling shows them to be treatments for various diseases, we determine the composition of those products, their ingredients, and go to the medical fraternity, generally, and learn their opinion of the truthfulness of such remedial claims. We encounter differences of medical opinion. If we do encounter such differences and there are, for instance, 80 percent of the physicians consulted who say that the product was a treatment under the outlined directions for use and 20 percent of them said it was not, there would be no case which the Department could bring. The reverse figures could be used. If 20 percent of them were to say it was an effective remedy and 80 percent that it was not, there would be no violation of the law.

Senator MCNARY. What is the percentage at which it becomes a violation of the law?

Mr. CAMPBELL. It must be almost 100 percent general agreement of medical opinion.

Senator MCNARY. Is that not impossible to acquire?

Mr. CAMPBELL. It is possible. I think with respect to a great many products it is. Here is a horse liniment. It is alright so far as liniments go. For purposes of this exhibition, I attach no significance to my designation of it as a horse liniment. But this is a horse liniment, and was prepared for use on horses.

The CHAIRMAN. Have you got any way to have that defined for and confined to horses?

Mr. CAMPBELL. The idea originally was, possibly, to have that done, but the formula for this liniment was sold to a manufacturer who began immediately to market it as a treatment for tuberculosis, cancer, locomotor ataxia, and other diseases, in fact for almost every imaginable disease. You can see by inspection how many diseases are listed.

The CHAIRMAN. In fact, what you mean by medical opinion is the conclusion resulting from scientific and clinical tests?

Mr. CAMPBELL. Oh, certainly. Senator, there would be no difficulty in finding out what the general agreement or the consensus of medical opinion is about the value of that liniment, composed of ammonia, eggs, and turpentine, for the treatment of tuberculosis.

It is a matter of extreme ease to do so. I know of but one physician who would testify that it was properly labeled, and he was brought forward as a defense witness in the trial of that case. Subsequently he was expelled from the local medical association. He was deprived, I believe, of his license to practice. There has been a tremendous amount of misunderstanding about the requirements of this section. That misunderstanding has been very adroitly developed and fostered. We have heard statements that you could not go to a drug store and buy aspirin tablets without getting a physician's prescription. Nothing is more absurd; nothing is more ridiculous or far-fetched.

The CHAIRMAN. When it is bought as a specific, not as a cure.

Mr. CAMPBELL. Aspirin is an anodyne and dulls pain. It ought to be sold with that understanding, and I think it is generally sold with that understanding.

I know that there are osteopaths who think if this bill passes they will be required to close up shop. There is no provision whatever to that effect. Such result is as far from the thought behind this bill or requirements of this paragraph as it is possible to be. There is nothing to that whatever. This has no possible relationship whatever to the creation of such a situation; this has no bearing on the differences of medical thought as expressed by different schools of medicine. The only thing the item does say is, if the labeling of the product is contrary—and note the significance of the word "contrary"—to the general agreement of medical opinion, it is a violation of the law.

Here is a product which it would affect. In connection with this liniment, the Department spent 10 years and $75,000 to bring about that modification of the label which you see by comparing the two bottles. It was imperative that we prove in court that the product was falsely labeled, that it would not have any effect whatever on the diseases which it was claimed to cure; also it was imperative that we prove that the manufacturer knew that it was not effective as a cure. We could not in the first battle prove that the manufacturer knew that it was of no value. We were only able to do it in our subsequent battles when we obtained evidence in connection with one of the testimonials which he incorporated in this circulars. It relates to the experience of one who had been taking his product as a treatment for tuberculosis. We showed that subsequently that person died from tuberculosis. Then, after her death, this person's son continued to write the testimonials in the name of his deceased mother, and we proved that they both received munificent donations from the manufacturer. That was ground to justify the jury in believing that the manufacturer acted fraudulently and knew that his product was worthless, notwithstanding his emphatic assertion of his personal conviction that the product was a cure for the various diseases listed on the bottle label.

Here is another product known as Banbar. It is recommended for the treatment of diabetes. This product is essentially a brew of horsetail weeds to be found in some sections growing along the railroad tracks. It was produced not by a person with medical knowledge, but by a former salesman of shirts. It has been sold widely. Unfortunately, it has been used extensively by the victims of diabetes. These sufferers did have available an effective agent for the pro-

longation of their lives in insulin, but they were persuaded to forego that, and become patrons of the manufacturer of this worthless nostrum. Some pitiful testimonials were submitted by the people who had been persuaded to buy and use this product. Subsequently some of these individuals died.

We tried that case. The Government lost. It lost because of the limitation of the law as it exists now, making it necessary for us to show that the manufacturer knew that his product was not a treatment for diabetes. Under present circumstances, a denizen of Central Africa, knowing nothing about administering to the sick, other than that imparted by the practices of a witch doctor, could land in this country, put up an article either of no more therapeutic value than a glass of water or as lethal as strychnine, sell it to the people of this country as a cure for every disease which man might have, and be within the terms of the law. His ignorance is his defense. The same product put out by some manufacturer with knowledge of medicine would be an offense under the law. But the effect on the public in either case would be the same. Through this provision of the bill, it would be possible to give far more protection to the public than can be done now. I think it is extremely important.

There will be interesting arguments, and there are going to be extensive references in the discussion here to this paragraph and its manner of operation. Under the terms of the present law we first undertook to control these medicinal products under the general misbranding provision. We took action against a cancer cure. The indictment was quashed on motion of the defendant and the case eventually went to the Supreme Court. The Supreme Court affirmed the decision of the lower court, holding that the terms of the act applied in nowise to remedial claims. That opinion was one which took into account particularly that portion of the sentence in the present law, page 17, section 8, reading, "That the term 'misbranded' as used herein, shall apply to all drugs or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article."

Mr. Justice Holmes rendered the majority opinion of the court, and after a scholarly dissertation characteristic of him, on the logical and idiomatic meaning of words, he concluded with this statement:

> It (Congress) was much more likely to regulate commerce in food and drugs with reference to plain matter of fact, so that food and drugs should be what they professed to be, when the kind was stated, than to distort the uses of its constitutional power to establish criteria in regions where opinions are far apart.

The whole purpose of that decision was merely to disclose the intent that Congress itself had in mind. The court held that Congress intended to have the language of the act apply to the identity of particular products, drug products, to statements made about matters of fact, such as what ingredients were there, rather than to the remedial claims. Congress, according to the statement of Justice Holmes, was not disposed to go into regions where opinions are far apart and establish criteria by which traffic in such products could be controlled.

There was a strong minority opinion rendered by Mr. Justice Hughes. I shall read two excerpts from it:

> The argument is that the curative properties of articles purveyed as medicinal preparations are matters of opinion, and the contrariety of views among medical practitioners, and the conflict between the schools of medicine are impressively described. But, granting the wide domain of opinion, and allowing the broadest range to the conflict of medical views, there still remains a field in which statements as to curative properties are downright falsehoods and in no sense expressions of judgment. This field, I believe, this statute covers.

Justice Hughes concludes with this statement:

> I entirely agree that in any case brought under the act for misbranding—by a false or misleading statement as to curative properties of an article—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion. Conviction would stand only where it had been shown that, apart from any question of opinion, the so-called remedy was absolutely worthless, and hence the label demonstrably false; but in such case it seems to me to be fully authorized by the statute.

The CHAIRMAN. Give us the citation.

Mr. CAMPBELL. United States Reports, 221 U.S. 488. The point I wish to stress here is that the majority opinion of the court was of the belief that the language did not undertake to regulate in any way therapeutic statements. The minority opinion was that it did undertake to regulate therapeutic statements in that field where questions of opinion were not involved because the statements were absolutely false; so much so that no difference of medical opinion could exist. As Mr. Justice Hughes said, conceding all the scope necessary for the entertainment of differences of opinion, certainly, there does come a point in this scale in which there are no differences of opinion, in which there is a unanimity of opinion about the worthlessness of a product. All we are asking in this particular paragraph in this bill, is that language be employed which will create no doubt in the mind of the court as was done in this case about the legislative intent. Let me say that immediately after the Supreme Court decision was rendered, there was no power left within the Department for the regulation of patent medicines. We could not give consideration at all to remedial claims of any nature. It was no offense for any manufacturer to market a worthless product as a cure for any disease. We could do nothing about it. Then Congress passed the Shirley amendment in 1912. That amendment did not prove to be a satisfactory solution. It holds that such products will be deemed to be misbranded——

The CHAIRMAN. Where do you find that?

Mr. CAMPBELL. In section 8, on page 18 of the present law.

The CHAIRMAN. Somebody wanted to know when we will adjourn. We will adjourn not later than 1:30 and reconvene not later than 2:30.

Mr. CAMPBELL. That language is:

> That for the purposes of this act an article shall also be deemed to be misbranded: In the case of drugs, if its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

It is imposed upon the Department of Agriculture the duty of proving that the manufacturer in telling a lie about his product, knew that he was telling such a lie. This was what we could not do in the case of this diabetes nostrum. What we are asking for in this paragraph is relief from that restriction. That is all that is involved in this provision. It will require the manufacturer of a drug product to determine whether it is or is not of value.

The CHAIRMAN. That would be subject to court appeal?

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Mr. CAMPBELL. Of course it would be. All action under this paragraph is court action. The Department would prefer a charge of misbranding in a case which would go to court and be tried on its merits.

Paragraph (b) is substantially what is in the law now. It names more narcotic products than those given in the present act, and it also contains the following:

> The Secretary is hereby authorized, by regulations prescribed after notice and hearing, to designate as narcotics or hypnotics within the meaning of this paragraph such other substances as he may find to possess narcotic or hypnotic properties.

This would permit the Secretary to include narcotics other than those named therein, as new ones appear. This is obviously in the interest of the consumer, and is not an imposition upon the manufacturer.

Section (c) is purely what is in the act now, because alcoholic or chloroform content is required to be shown on the label. These products usually are present in such small quantities that they are not habit forming.

The CHAIRMAN. Does the repeal of prohibition have any reference to the use of alcohol?

Mr. CAMPBELL. No, sir.

Paragraph (d) is merely to require that directions for use be stated on drug labels. That paragraph (d), of course, should be read in connection with section 4 (a), which refers to the use of drugs. It makes compulsory the use of a label.

The CHAIRMAN. We will take an adjournment for one hour, to reconvene at 2:15.

(At 1:15 p.m. an adjournment was taken until 2:15 p.m.)

AFTER RECESS

The subcommittee met at the expiration of the recess, at 2 o'clock p.m., Senator Copeland presiding.

Senator COPELAND. The committee will come to order. Before asking Mr. Campbell to return to the stand, there are two or three gentlemen present who must return to the East and they are proponents of the bill. Although it will be out of order a little, we will call on them now. The first one is Professor Henderson, of Yale University. Professor Henderson.

STATEMENT OF PROF. YANDELL HENDERSON, PROFESSOR OF APPLIED PHYSIOLOGY, YALE UNIVERSITY, NEW HAVEN, CONN.

Professor HENDERSON. Mr. Chairman, I appreciate very highly your courtesy in allowing me to interrupt Dr. Campbell, and, in return, I am going to try to be as brief as I possibly can and deal only with a few specific matters so as to leave time for my colleagues. Dr. Freeman and Dr. Haven Emerson, who are also to speak during this pause in Dr. Campbell's testimony.

I have a rather extensive experience, running over many years, in relation to certain aspects of public health and the hazards to health, and even to life from substances that are not now under, but that ought to be under, the Food and Drugs Act. I know of cases in

which illness, or even death, has occurred from inadequate protection because of the inadequacy of the present law. The Food and Drug Administration has been subject to criticism for not doing certain things that they are prevented from doing by the weakness of the present law. I agree absolutely with all that Dr. Campbell said this morning. It was entirely in accord with my experience. For this reason I have come down here to support the strengthening and revision of the Food and Drugs Act.

I want to dwell on just one or two specific points. There is a new drug just now being introduced called "dinitrobenzol." I wonder that it is not on the market already in patent medicines. It takes only a little to make the metabolism, the combustion in the body, go up 10 or 15 percent or more. The man or woman that takes it loses weight rapidly. It would be a wonderful antifat medicine. But if the patient increases the dose and takes too much, as some certainly will, the combustion goes up, and so extremely that the temperature rises, not only 4° to 5° as in an ordinary fever, but 9° or 10°. Within 24 hours that patient has practically burned himself to death. That will happen often unless the Government controls the use of that drug in patent medicines.

Against such drugs the present law does not give protection. Under the provisions of the revised act that Dr. Campbell described this morning there would be protection.

The particular reasons that I have appeared at this hearing are two; first, I have been brought into contact with cases of injury to health, and even to life, by preparations that go into the American homes against which neither the present law nor the bill before you, as now printed, affords adequate protection. This experience enables me to see how important and how necessary is the protection that the present law does give, and how beneficial will be the increased protection that the revised law will give.

Secondly, while I am a supporter, to the last comma, of this bill, I have come here also to urge that its provisions should be expanded and extended sufficiently to protect the American home against household preparations that sometimes do quite as much harm as any adulterant in food preparations.

One class of such substances has been dealt with in a special act, the so-called "Corrosive Poisons Act", passed 5 or 6 years ago. Before that such substances as soda lye and ammonia and oxalic acid, that women use to clean the kitchen sink and to polish copper, were sold with no warning label; and it was a common accident for young children to get hold of the can and swallow some of the contents with the result of death or lifelong injury.

This kind of accident used to happen frequently and is now provided against. But there is another group of hazards and accidents against which there is as yet no protection and for which I think this revised bill should give protection.

I will touch on only two or three. One of these substances occurs in polishing powders and in the liquids used to clean forks and spoons. Three or four years ago there were a number of cases of severe illness, and my personal belief is there were some deaths, from minute amounts of silver polish left on the forks and spoons.

It was very puzzling, for at first no one suspected the polish; everyone suspected some food, until one of the men from the United States

Public Health Service in going through the pantry of a hotel smelt the odor of bitter almond, the odor of cyanide. He followed this up and found that the cases of poisoning were due to the silver polish. It contained potassium cyanide, an excellent substance to clean silver forks and spoons but also one of the most deadly poisons.

There is nothing in the present Food and Drugs Act, nor in the proposed revised act, to prevent an enterprising manufacturer from putting cyanide silver polish on the market under a succession of fancy names.

Dr. Campbell spoke of beans that produced cyanide. I submit that it is not only important to avoid beans from which one can get cyanide, but it is equally important that one should not get cyanide from the fork with which one eats the bean.

There is one other point in connection with the discussion this morning on which I would like to touch; that is the question of presumption of innocence. Certainly the law will always presume an individual innocent until he is proved guilty. But I want to protest against assuming innocence in a ketchup containing a poison until it is proved guilty by killing some one. I protest against a silver polish containing cyanide being assumed to be innocent until it is proved that that polish has caused a death. Cyanides should be presumed guilty even before they have taken a life.

The same general statement is true of another substance, sodium fluoride, which is commonly sold to be scattered about the pantry or kitchen if there happen to be some ants in the floor or some water bugs around the sink. Sodium fluoride is a powerful poison. It has caused deaths.

Senator COPELAND. I remember some sodium fluoride being sold as roach powder. A distinguished citizen sent out for some headache powder, and for some reason they sent him roach powder and he died. We found that there was no provision made for labeling that package as poisonous or indicating how dangerous it might be. So I know of one case where death has occurred from the use of that substance.

Professor HENDERSON. I am delighted to have my statement confirmed by the Senator. I might mention that I found sodium fluoride in my own kitchen some months ago. The control of sodium fluoride insect powder to be used in the home is not covered either by the present law or in the proposed bill.

This is true also of floor wax containing carbon tetrachloride and related substances. Children playing on the floor have been overcome by the fumes which are poisonous.

Against none of these and many similar health hazards to the American home does the present law or the proposed law afford protection. Yet all these household preparations are bought from the same store and are delivered in the same market basket as the food preparations that are covered by the present law and which will be even better safeguarded under the proposed law.

I shall not take your time to discuss other examples of household health hazards. I offer for the record, a talk that I gave on the radio a short time ago on household health hazards that deals with these matters.

Senator COPELAND. That will be included in the record.

(This radio talk follows the direct testimony of this witness.)

Professor HENDERSON. I would like also to call attention to a hearing before a committee of the Senate a couple of years ago on a bill to control volatile poisons. I am not going to bring up the details of that bill. I merely want to call attention to the fact that it was shown by experts and authorities like Dr. Aline Hamilton, of Harvard; Dr. H. Gideon Wells, of Chicago; Dr. C. E. A. Winslow; Dr. Leach, director of the American Medical Association Chemical Laboratory; and Dr. Cary McCord, that the type of hazard to the American home I am speaking of does exist and the home has no protection.

Senator COPELAND. Let the record show the reference to this particular document, so that it may be referred to in the future.

Professor HENDERSON. I have here the report of the hearing before the Committee on Agriculture and Forestry, United States Senate, Seventy-second Congress, first session, on S. 3853, a bill to regulate interstate and foreign commerce in poisonous and volatile substances intended for household consumption.

I might mention that the scientific basis of that proposed law was drawn by me and it was put in shape by the legislative counsel of the Senate and was introduced by Senator Bingham. I am now only calling attention to that part of the testimony which dwells on risks to the American home which are not now covered.

All that is necessary to bring these household preparations within the terms of the revised Food and Drugs Act is a paragraph to be inserted on page 2 between lines 17 and 18 to the effect that the term "household preparation" means all substances and preparations for the cleansing, polishing, preservation or improvement of the appearance of the home or any of its equipment, or the closing of its occupants, or any other use about the home.

In addition, in line 9, on page 3 and elsewhere, the words "household preparation", and then on page 12, before the words "false advertisement" the insertion of a section defining the misbranding of household preparations in terms almost exactly identical with those applied to foods in section 7 and to drugs in section 8.

If this addition is made, the revised act will cover practically the whole field of the protection of the American home from drug and food preparations, cosmetics, and these household preparations that I have been speaking of; but until this is done, the protection afforded to the home will remain incomplete.

There are just one or two other points on which I would like to touch. On page 10, line 15 to 18, require that the amount of alcohol contained in any drug should be stated on the label. I did not catch the discussion of that this morning. I do not suppose that as it stands this requirement applies to beer or wines or cordials or spirits; but, in my judgment, it would be extremely advantageous if the requirement of the percentage of alcohol were extended to include all beverages as well as all drugs. It is time that the American people learned the difference between 50-percent alcohol and 4-percent alcohol, or 3.2 percent, and that the effects of alcoholic beverages are determined by the amount of alcohol and not by the color of the beverage.

Then, finally, there is one other point that I picked up during Dr. Campbell's testimony, and that is the fact that the new bill is to include physical-therapy appliances. I can speak with heartfelt earnestness on that matter because I happened a few months ago to have been appointed on the Council of Physical Therapy of the American

Medical Association, and we constantly have referred to us all sorts of physical therapy appliances. All we can do is to approve those that are really good and then they may be advertised in the journal of the American Medical Association. Those that are not useful, or those that are distinctly harmful, we can merely reject.

The Food and Drug Administration will be able to go much further and discredit the marketing of those that are distinctly harmful, and it will relieve the Council of Physical Therapy of the American Medical Association of a duty or a function which it now tries to fulfill. We do the best we can, but we are certain that the Food and Drug Administration can do it much better.

To sum up, my experience with those matters that are not covered by the present law, but that should be covered by the revised law, shows how immensely important and how necessary protection is in those matters that are covered, and how much needed in those that are not covered. On these grounds I strongly support and urge the passage and approval of the revised Act, and the additional features that I have here discussed.

Science Service Radio Talks

Presented Over the Columbia Broadcasting System

Household Health Hazards

BY DR. YANDELL HENDERSON

I am going to talk over with you some of the dangers that we are all exposed to nowadays. We all realize the hazards to life and health that the automobile has introduced, for many people are killed even in trying to cross the street. But the dangers that we are going to consider now are not so well known. They are quite largely hazards to health and dangers to life that occur in our homes.

Nearly all these dangers have developed rather recently. They are nearly all due to advances in science. You know that the advances in medical science have greatly decreased the deaths and illness from infectious diseases. The applications of medical science have made life much healthier and the average life much longer. A generation ago diseases like typhoid fever and diphtheria caused a heavy death rate, while now in a town or city with a good health department a year may go by with few or no deaths from these diseases. To a large extent this advance has been made by the health departments of our cities, our States, and the National Government. It is the fashion just now to criticize the Government for costing so much and for requiring high taxes to support it. But the truth is that the service that the National, State, and local governments render us simply in protecting our health is worth every cent we ever pay in taxes. It would be a disaster, if the effort to decrease the expenses of our various governments resulted in crippling the public health services.

We know that the police protect our property and our lives from criminals; that the fire departments protect our homes from fire; and that the United States Army and Navy protect us from foreign enemies. But we seldom think of the protection that the Government gives us in regard to the food that we eat and that it should give us in regard to certain hazards to which our homes are now exposed. The most important protection of this sort is that afforded by the Federal pure food law, and similar laws in the States together with the arrangements that the Government maintains to see that the pure food laws are obeyed. The agricultural experiment stations in many States are every day analyzing samples of foods that are being sold on the open market and these results are published in the reports of these stations. Impure foods are confiscated and destroyed. You can get one of these reports by writing to your State government.

Before the pure food law was passed any food producer could sell nearly anything that he could persuade the public to buy, no matter how much his product was misrepresented. I remember some strawberry jam that was highly advertised as a superior product, but it was found to consist of apple butter sweetened with corn syrup, flavored with a synthetic chemical flavoring, colored with a coal-tar dye, with artificial wooden seeds scattered through the jar. The one thing that that jam did not contain was strawberries. It was like the wooden nutmegs that were once said to have been manufactured in Connecticut, where I live. I doubt the story about wooden nutmegs, but until the pure food law was enacted there were sausages made that had almost no sausage meat in them. And then there was the so-called embalmed beef that was alleged to have been supplied by some of the big packing houses to feed the soldiers in the Spanish War. I don't know whether Theodore Roosevelt, when he led the Rough Riders in Cuba back in 1898, ever ate any of that embalmed beef, for our soldiers in that war had very little to eat of any sort. But when he became President one of the measures he got Congress to pass was the pure food law. There was, of course, great opposition from some food producers on the ground of bureaucracy and interference with freedom of trade. But the law was passed and it has really been almost as valuable to producers and merchants as it has to consumers. It has not only prevented many cases of food poisoning and swindling by sale of inferior products; but it has also greatly increased the sale of all sorts of canned goods and foods in packages. So long as there was doubt of the purity and healthfulness of such foods people hesitated to buy them. Now they are sold in immense quantities, for every package of breakfast food, every can of vegetables and every bottle of pickle on the market is now subject to the superivsion of the Federal and State Governments. All food products are required to be free from adulteration, and the label on the can or package must tell the truth about the contents.

Another big step to protect the American home was taken three or four years ago when Congress passed and President Coolidge signed a law called the Corrosive Poisons Act. This act requires a warning label on various chemicals and cleaning fluids that are used to clean nearly every home. One of these substances is soda lye that is used to clean the kitchen sink. Every now and then a little child got hold of the can and swallowed some of its contents. The result was fearful injury, lasting sometimes throughout life, even if the child was not killed immediately. All such substances must now bear a warning label, and many accidents are thus prevented.

But this is not yet enough. There are still many substances that are sold and that are very useful but which carry dangers into our homes. And against these substances, some of which are very poisonous, there are as yet no protective measures and no requirement for a warning on the label. A couple of years ago many cases of illness, and perhaps some deaths occurred in hotels, and some may have occurred also in private homes, where the forks and spoons were cleaned with a silver polish containing the deadly poison potassium cyanide. A few grains of this polish between the prongs of a fork were enough to cause serious illness. There was no warning on the label of that silver polish. It has been withdrawn from sale. But it was an excellent polish, and there is nothing now to prevent another manufacturer from putting out a similar polish containing postassium cyanide under a fancy name.

There is now on the market a powder for cockroaches. It contains sodium fluoride and has killed several people who took it by mistake. It is sold in a package that looks like that of salts. It has no warning on the label.

The largest group of poisonous substances that now go into our homes without any warning of their dangers are various volatile liquids and new chemical substances that are each year invented by chemists, and put on the market and sold to the public, before any test has been made as to whether they are poisonous or not. For such substances there is as yet no requirement that the label shall give warning of danger. One of these substances that is very useful for cleaning purposes is carbon tetrachloride. Now let me say at once that carbon tetrachloride has certainly saved more lives and health than it has destroyed or injured. It is very much safer to remove grease spots with this liquid than it is with gasoline or naphtha, for carbon tetrachloride does not catch fire. It will not burn; but many a woman has been badly or even fatally burned by gasoline. On the other hand, carbon tetrachloride has a vapor that is distinctly poisonous. The substance should be used only in well-aired places so that the user does not inhale the fumes. In Switzerland carbon tetrachloride has been used as the solvent for a floor wax in a school. It caused serious illness. There is now no law or regulation in America to prevent carbon tetrachloride and similar new substances being used in floor polish. It can cause serious illness in children playing on a floor polished with such substances. There is no requirement now for a warning in the label on the can. It is not sold to the general public as carbon tetrachloride but under a fancy name. The next time you buy a bottle or can of cleaning fluid ask what it really is. In fact, when you buy any chemical for use in your home always find out what the constituents really are.

I do not want to give you the impression that American manufacturers wish to poison those who buy their products. They do not. They are humane men, and deaths or illness caused by their products react against selling their goods. The harm comes from the fact that when a new substance is invented by chemists and is found to be useful for some purpose, it is manufactured and sold without any investigation of whether its use involves hazards to health and life. Chemists had been looking for a substance that would prevent automobile engines from knocking—that is, from premature explosions in the cylinders and loss of power. At last an effective substance was found to be tetraethyl lead; and the manufacturers were about to distribute it all over the country to be added to gasoline at filling stations. Fortunately, scientific men who knew that tetraethyl lead is a powerful poison were able to warn the manufacturers in time. As a result the substance, instead of being distributed in concentrated form, is now mixed with the gasoline at petroleum refineries and distributed as "ethyl gas", which is relatively safe. Warnings are also put on the pumps at filling stations. There have been few or no cases of posioning since these precautions were put into effect; but without these precautions there would almost certainly have been hundreds of cases of poisoning.

Another substance, methyl chloride, has, however, caused a number of deaths. This liquid or gas is used in some makes of automatic refrigerators. These refrigerators are certainly a great convenience as compared with the old-fashioned ice refrigerators. They are also quite safe if they are made in single units. Methyl chloride in a single unit refrigerator is perhaps safer even than most of the other gases that are used. But, unfortunately and unwisely, multiple systems of refrigerators were allowed to be installed in big apartment houses in some cities. Such an installation involves a big storage tank or cylinder of the refrigerant in the basement connected to many refrigerators in the various apartments. If any one of the refrigerators in any one of the apartments develops a leak the whole of this large amount of gas from the cylinder and from all the other refrigeratorsin the building escapes into that one apartment. This occurred in some apartment houses in Chicago and caused a number of deaths a year or two ago. Large multiple refrigerator systems are dangerous. Single units are safe.

I could easily tell of other examples of the household hazards that modern scientific conveniences have introduced into our homes. The electric light fixtures in a bathroom should always be so arranged that no one can make contact with a live wire with one hand when his other hand is in a wash basin or his feet in a bath tub. Cases of death by electrocution by the house current have occurred under such conditions.

There are also the dangers from the city gas that we cook with nowadays. Old and defective rubber tubes leading to gas stoves are liable to break and to allow the gas to escape. Deaths from this cause are common. Water heaters, if badly arranged, may also produce carbon monoxide. Every gas heater should be connected with a chimney to prevent this danger. Another common danger nowadays is that from carbon monoxide in automobile exhaust gas. Never start the engine of your car, no matter how cold the weather, until you have opened the garage doors.

Senator COPELAND. We are very much obliged to you, Professor Henderson. I will now ask Prof. Allen Freeman, professor of health at Johns Hopkins University, to speak to us.

STATEMENT OF PROF. ALLEN FREEMAN, PROFESSOR OF PUBLIC HEALTH ADMINISTRATION, JOHNS HOPKINS UNIVERSITY, BALTIMORE.

Professor FREEMAN. Mr. Chairman, like Dr. Henderson, I thank you very much for the privilege of speaking out of order. I shall try to be as brief as possible.

I have only a few words to add to what Dr. Henderson has said: First of all to express my entire agreement with the purpose and scope of this revision of the pure food bill.

It was my privilege over a period of some 14 years to serve as a health officer in one jurisdiction or another and to sit, so to speak, at the receiving end of some of these food-poisoning episodes.

I happened to be the responsible officer in charge of the first botulanous epidemic. It was my very unfortunate function to have to preside at the funeral of the ripe olive industry. There was no cooperation whatever from the manufacturers of the particular brand of olives which caused this epidemic. There were cases of this particular lot in half a dozen Ohio cities, and no one knew in how many other parts of the United States. There was only one thing to do, that was to advise the people of Ohio not to eat Curtis ripe olives. I was subsequently visited by a lawyer representing the manufacturing concern that did me the compliment of threatening to sue me for half a million dollars. There was no suit, of course. That destroyed that industry. This particular firm did not belong to the trade association, and this firm had refused to conform to the simplest requirements necessary to insure the safety of their customers. They went down and the great industry was for a time completely destroyed. No one can serve as health officer without being impressed with the very great necessity for the most rigid control of food products.

Senator COPELAND. Will you pardon me if I interrupt you? Would it not be wise for the comfort of people who eat ripe olives to say that the conditions of sterilization and preparation have now been perfected to the point that the danger which arose in connection with the epidemic mentioned is not likely to recur?

Professor FREEMAN. Quite. I am sorry I did not make that plain, Senator. The Organized Trade Association took hold of the problem and within a few years ripe olives were perfectly safe to eat and have been ever since. I cite that only as an example of the dangers which result from ignorance, whether intentional or otherwise, of the principles of protection.

Now, I am sure anyone present here who had seen the victims of that epidemic would have felt that no precaution, however burdensome it might be on that industry, would be too great to prevent a repetition of that occurrence. It was a perfectly dreadful thing.

I think we have to recognize in looking at this bill that the purpose of most processing and what you may speak of as elaboration or sophistication of food is to increase sale, either through improving the appearance of the product, through dividing it into attractive units so that a higher price for the same amount can be obtained; or, as is frequently the case, through reducing the cost of production by providing an inferior product.

When we confront situations like these it seems to me beyond question that the consumer has a right ahead of the profit. I have no objection to profits in the food industry. We could not have food without that, but we must consider the rights of the consumer first last, and all time.

Then, with reference to this matter of lead tolerance about which there was some discussion this morning; at the present time it is possible for the Food and Drug Administration to regulate the amount of lead on apples or on peaches so that if you confined yourself to apples or peaches you would not get an excessive amount of lead.

The same thing is true of fresh vegetables, such as cauliflower and cabbage. If I happen to be fond of apples, cauliflower, and other things on which this arsenic and lead is used, the fact that each one of them is individually safe does not mean that the combination is

safe. In very truth there must be an allocation of the amount of arsenic which can be used in the different products we have to eat.

Senator COPELAND. Professor Freeman, have not those tolerances with reference to arsenic and lead been so well established that we might now determine by law what should be the limit of use?

Professor FREEMAN. I hardly think you could determine it permanently by law, Senator, because there are constantly new products coming into the market on which they have been used, and the tolerance permitted on any product is dependent on how many other products have to share in this lead.

So far as cosmetics are concerned, I think every one who has seen the results of some of the cosmetics now on the market will agree that some form of regulation is necessary; and, while we do not want to interfere with anybody paying $3 for a small amount of perfumed lard if they wish to, we do not want them to be sold anything that is going to take the hair off their head or ruin their vision or produce horrible scars.

So far as patent medicines are concerned, I feel very strongly on the subject because all must recognize that most of them have no value whatever; that what gives them value is not the formula, not the content of the drug which they contain, but the advertising to which they are attached.

I had the misfortune once to make an indiscreet remark about a new cure for tuberculosis. The remark was repeated in the newspapers and for weeks thereafter my mail was flooded with the most pathetic letters from consumptives all over the country. There are thousands of these people suffering from incurable diseases, and we must protect them from the kind of exploitation to which they have been subjected in the past and to which they are now being subjected. Based on my knowledge as a health officer, Mr. Chairman, I want to go on record as favoring the new features of this bill as necessary to the protection of the public health.

Senator COPELAND. Have the washing methods for apples and pears done very much to give safety?

Professor FREEMAN. We have been having a great deal of trouble in Maryland in keeping the apples which are being shipped out of Maryland to England within the limits of tolerance which are accepted by the English authorities. It is a very difficult thing to get the arsenic off if too much has been put on.

Senator COPELAND. Even where certain chemicals have been used with the water do you still have some difficulty in cleansing the fruit?

Professor FREEMAN. I have not had any particular experience with those methods. I have been familiar only with the general course of events. But I was talking with the doctor who has charge of the matter in Maryland a few days ago, and he was very much discouraged at the outlook.

Senator COPELAND. I thank you very much, Professor. I appreciate your coming. I will call now on Dr. Haven Emerson, representing the American Public Health Association.

STATEMENT OF DR. HAVEN EMERSON, REPRESENTING THE AMERICAN PUBLIC HEALTH ASSOCIATION

Dr. EMERSON. Mr. Chairman, I bring for your consideration two resolutions, one from each of the professions chiefly concerned, and both in favor of the principles expressed in the bill. The resolution of the American Public Health Association came from its food and drug section which represents those persons who are in official positions as well as in the industry and this is endorsed by the entire public health profession of our country. I leave this with you for the record.

Senator COPELAND. It will be included in the record.

(The resolution referred to is as follows:)

At the annual meeting of the American Public Health Association in Indianapolis in October of this year, the following resolution was passed:

Whereas the present Federal Food and Drugs Act has brought a high measure of protection to the American public through its faithful enforcement by the Food and Drug Administration officers, and

Whereas due to changing methods of manufacture and distribution of food and drugs the act needs revision to maintain and increase public protection; therefore be it

Resolved, That the American Public Health Association—

1. express its confidence in the purposes and principles of the proposed revision of the Federal Food and Drugs Act now before Congress for action; and
2. solicit the support of all members of the association to secure the enactment into law of the objectives of this revision, and
3. that this expression of the views of the association be made a part of the record of this meeting.

Dr. EMERSON. On Monday, December 4, the New York Academy of Medicine similarly took cognizance of this bill and passed a resolution expressing the considered opinion of the clinicians and the hospital physicians and others of the city of New York. It reads as follows:

Resolved, That the New York Academy of Medicine, through its public health relations committee, express its whole-hearted approval of the fundamental principles underlying the proposed Federal Food and Drugs Act (S-1944) and register its conviction that the proposed legislation is a forward step toward the protection of the health of the citizens of the United States.

As President of the Public Health Association and a member of the public health committee of the academy, I advise you that we are constantly observing at the medical centers in New York through the departments of Dermatology and Medicine the victims of the injudicious use of self-beautification efforts who come to us with many pathologic conditions: Patients with deformed faces, patients with poisoned bodies, patients suffering at long time distance from the time when they used their medications from chronic poisoning, which they could not themselves suspect from their own symptoms at the time of using the cosmetic. A matter which I think should be emphasized in the discussion of this bill is the chronicity, the long interval between the time of the application of these preparations and the beginning of symptoms which makes it impossible for the individual consumers to protect themselves as they would against some violent irritant applied to the skin. Lead, silver, and arsenic are common types of chronic poisoning by cosmetics.

I should like to offer one or two brief suggestions for the improvement or strengthening of the effect of the bill. One of them is the addition of the word "contemporary" in two places which I will call to your attention. On page 9, line 22, after the words "agreement of" add the word "contemporary", making it read "agreement of contemporary medical opinion."

Having been called as a witness in various cases in the enforcement of the present Food and Drugs Act, I have found the court and other

witnesses confused by the quotation of medical opinion which has been long discarded and recognized as inacceptable at the present time. It is important to use the phrase "contemporary medical opinion", because nowadays medical opinion does not follow by tradition but science.

Senator COPELAND. I want my colleagues on the committee to realize that medicine is a progressive science.

Dr. EMERSON. We physicians are apt to assume that this is understood, and from time to time it needs repeating.

Senator COPELAND. It is well to have it written into the law, however.

Dr. EMERSON. The same word on page 13, line 6, is called for before the word "medical", the last word in the line.

Now, beyond that my other suggestion is with reference to section 22 which appears on page 29. This section is of great importance because it proposes a friendly cooperative and helpful relationship between the suggested inspectorial functions of the Government and the necessary self-protection of the producers.

I should like to suggest that there is a further need which can be met by existing Government facilities if it is provided that the testing of new and untried drugs and mixtures be a responsibility of the Government at the request of the manufacturer. At present a manufacturer has a difficult time with the very best intention to be honest and effective with his expected consumers. He has a difficult time in having new substances, new drugs, biological or chemical in nature, tested so that he will know by laboratory observations whether or not they do harm before they have been tried on the human guinea pig. At the present time the consuming public is the testing laboratory, and until some damage has been created to the human there is no criticism. It is important that the Government make available its facilities for testing these new materials before they are marketed, instead of simply using their power of prosecution after the damage has occurred.

Senator COPELAND. Dr. Emerson, you will recall that in the bill providing for the establishment of the Institute of Public Health it was provided that there should be such laboratories that would carry out what you have in mind, but you think that there should be some provision made in this bill for that?

Dr. EMERSON. I believe there should be an obligation put upon the Government to provide such a service. Whether that can best be done in the National Institute of Health or whether in the laboratories of the Bureau of Chemistry of the Department of Agriculture, I will not attempt to suggest: but I believe the Government should be charged with the duty of providing a place in which a manufacturer can obtain the best skill to determine whether what he proposes to sell is likely to do any damage to the people using it.

Senator COPELAND. I am in the fullest accord with you in the suggestion, but the idea is contained now in the law establishing the Institute of Public Health, and the difficulty there is the lack of appropriations to do the very wise thing that you suggest.

Dr. EMERSON. It was for exactly that reason that I suggested it being mentioned in section 22, which section presents a very interesting innovation of public practice. This section suggests that a manufacturer can request inspection and pay for the cost of it so that he will know that the products he issues are valid and properly manufactured.

Senator COPELAND. Dr. Emerson, did you formulate some language to cover this point?

Dr. EMERSON. No, Mr. Chairman; this is a suggestion of a principle. I have no skill in legal phraseology, but I believe that this is an appropriate place to improve the text of the bill.

Senator COPELAND. A note will be made of your suggestion and consideration given to it.

Dr. EMERSON. In closing I have merely to say that I believe there is practically unanimous opinion among physicians dealing with clinical medicine in New York that we are unable at the present time to protect our patients and our families against the hazard of poisoning and damage to health by cosmetics and drugs and by the sophistication of foods without the provisions that are made in this proposed law. As a teacher of public health I find provisions written into this law practical and each one of them indispensable to the proper administration of a service necessary in the interest of public health. We could not do the necessary job of health protection without all of the provisions that are made in this bill. I believe they are practical and will be effective if put into force.

Senator COPELAND. Thank you very much, Dr. Emerson.

We will now hear from a representative of the American Federation of Labor, Mr. Roberts.

STATEMENT OF MR. W. C. ROBERTS, LEGISLATIVE REPRESENTATIVE OF THE AMERICAN FEDERATION OF LABOR

Mr. ROBERTS. Mr. Chairman, I am here to approve in the name of the American Federation of Labor the legislation which is proposed. In order to show what has been done by the American Federation of Labor, I wish to refer to a report of the executive council at the Atlanta (Ga.) Convention in 1911. The report states:

> Due to untold greed, the health and the lives of the people of our country have been placed in jeopardy through the adulterations and substitutes in the foods and the drugs sold to the masses of our people. The Congress of the United States enacted laws for the better protection of the people in regard to this traffic by the passage of what is known as the "pure food law", 5 years ago. Those who have profited, and still profit, by the imposition upon the people of impure foods and drugs, have become more active in the recent past; they have perfected combinations by reason of the great profits resulting from their traffic and have endeavored to circumvent the law, even to the extent of trying to remove a faithful public officer who has stood between them and the people. When such men in their greed for profit alone endanger the health and the lives of myriads of men, women, and children—the workers—the duty devolves upon our movement to take such action as shall safeguard our own.
>
> With this object in view, taking cognizance of the efforts made by other associations of men to be of service to the people in regard to this movement, the executive council at its recent meeting adopted the following:
>
> *Resolved*, That the executive council appoint a committee of three to meet with representatives of all bodies and persons having for their object the securing of legislation or administration to secure pure food and pure drugs for the people of this country.
>
> We have selected President Gompers, Vice President O'Connell, and Secretary Morrison as the committee.

Senator COPELAND. Was that report made, Mr. Roberts?

Mr. ROBERTS. In 1911, at the Atlanta (Ga.) convention, 5 years after the original law was enacted.

On the executive council at that time were:

Samuel Gompers, president; James Duncan, first vice president; John Mitchell, second vice president; James O'Connell, third vice president; D. A. Hayes, fourth vice president; William D. Huber, fifth vice president; Joseph F. Valentine, sixth vice president; John R. Alpine, seventh vice president; J. B. Perham, eighth vice president; John B. Lenon, treasurer; and Frank Morrison, secretary.

This report of the executive council was referred to the committee on resolutions, which made the following report to the convention:

> Your committee commends the action of the Executive Council of the American Federation of Labor in connection with the efforts being made to secure the passage of laws and other enactments which would prevent the manufacture or sale of any articles of food or drugs which were adulterated or placed on sale under misleading labels or advertisement.

The report of the committee was unanimously adopted.

In 1912 the executive council's report to the American Federation of Labor stated:

> The American Federation of Labor has continued its efforts along the lines of having enacted better pure food and pure drugs laws, and in this work has cooperated with the American Society of Equity, the National Consumers' League, and other reform associations interested in and working along similar lines.

In 1915 the American Federation of Labor adopted a resolution urging legislation requiring the transportation of all foodstuffs in clean receptacles to better safeguard public health.

If this bill carries out what the American Federation of Labor has determined could be done, we approve it gladly; but if it means any changes for the better we hope certain changes may be made.

Senator COPELAND. Now, Mr. Campbell, you may proceed.

STATEMENT OF MR. WALTER G. CAMPBELL, CHIEF OF THE FOOD AND DRUG ADMINISTRATION OF THE DEPARTMENT OF AGRICULTURE—Resumed

Mr. CAMPBELL. At the time of adjournment for lunch, Mr. Chairman, I think we had concluded those paragraphs in section 8 down to paragraph (*e*) which is to be found on page 11.

This paragraph requires a declaration of the important ingredients of drug products. It states that a drug product would be held to be misbranded if not subject to the provisions of paragraph (*b*) of section 4, relating to official United States Pharmacopœia and National Formulary products if it fails to bear first the common name of the drug, if any there be; and, second, the name and quantity or proportion of each medicinal or physiologically active ingredient thereof. The paragraph explains itself.

Its purpose is to give to the consumer knowledge of the composition of the product that he is going to take for the treatment of his ills. I know of nothing in the entire scope of this bill which will operate more effectively to dispel the mystery now so extensively capitalized in the sale of nostrums for every imaginary disease than a declaration on the labels of the ingredients of which a particular nostrum is composed.

. That mystery developed adroitly and effectively, through the medium of advertisements which appear in the columns of the press, and

are heard over the radio, constitutes the principal urge for the purchase of drugs for self-medication.

There is no issue, as I have told you previously, from the standpoint of the enforcement of the Food and Drugs Act about self-medication.

This bill does not contemplate its prevention at all. If it did a single short section in the measure could have been drawn up to that effect. But what is desired by this particular paragraph and by others which impose restrictions on statements made about the remedial properties of drugs is to make self-medication safe.

There always will be self-medication to some extent. As I have said, from our law enforcement standpoint we do not object to it, but it should be intelligent; it should not be based on a faith created by a supposition, usually an erroneous supposition. I have already exhibited to you some of the products which are now sold for the treatment of serious diseases and which have no remedial power for the treatment of those diseased.

It is alleged in connection with this particular section that it is extreme; that it calls upon a manufacturer to make a surrender of property rights in which he has a definitely vested interest; that it requires disclosure of trade secrets. To a large extent that is sheer nonsense. Competitors through observations, expert analysis and other investigations that may be carried out can easily ascertain the essential composition of various drug products to be found on the market.

The ingredients are not secrets, but there is, I will grant, in the preparation of such products manufacturing technique which may be of value to manufacturing firms. I have had manufacturers of drug products tell me repeatedly that there was no objection to this requirement; that it was not the ingredients or the composition of the article which constitute the secret, but rather the method of combining the various ingredients.

It is important from the standpoint of those who seek to protect themselves by intelligent purchasing that they have information of the ingredients in drug products in order to forego ills and distress which they would otherwise experience. There are a large number of drug products for which many people have idiosyncracies which prevent them from using such drugs effectively or comfortably. It has been alleged that the psychological benefits to be derived from lack of knowledge of the medicines which one takes, plays an important part in the improvement of people who are sick. Again, to my mind, that is sheer nonsense. There may be some value in refusing to disclose to the patient the medicine that may be prescribed to him by a physician: but bear in mind that when the patient himself purchases a prorietary product, or a drug that is designed for self-medication, he stands in respect to himself as self-diagnosing and self-prescribing. He is entitled in such circumstances to the same sort of information that the physician has when the physician administers to him.

This requirement is not new; it is not an innovation. There are a great many countries in the world at the present time that impose requirements of this sort. Among those nations that require a quantitative declaration—and that is essentially what is being proposed here—at the present time as revealed by a very brief and cursory review of the laws of the foreign countries are Chile, Denmark, Fin-

land, Guatemala, Italy, Mexico, Nicaragua, Sweden, Uruguay, Yugoslavia, and the Philippine Islands.

Those that require a qualitative declaration and enumeration of the ingredients without an indication of the quantity in which they are present, include Argentina, Belgium. Costa Rica, El Salvador, France, Panama, Peru, Portugal, and Spain.

That is not all, Mr. Chairman. There are some manufacturers in this country who voluntarily have met in principle if not in letter the requirements of this section. Dr. Kilmer's "Swamp Root" is an illustration. You will find on the carton here the ingredients of which that product is composed.

All manufacturers exporting medicinal products to the countries to which I have referred declare the formulas quantitatively or qualitatively.

Let me present to you an identical product in two different packages. One is to be marketed in the United States for the consumption of the people of this country. The other is for export. You will note that on one of these there is no disclosure of the ingredients. That is the one intended for home consumption. On the other there is a statement of the formula, in such terms as the country to which it is to be exported may require.

Senator COPELAND. That package is identical, but there is attached to it a typewritten formula to meet the requirements of the country to which it is to be sent.

Mr. CAMPBELL. The formula is printed on the label and in that particular instance in a very inconspicuous place. The typewriting to which you refer is a translation into English of that formula in order to bring out more definitely the composition of it. The same is true of these others. I have had that typewritten statement placed on there, Mr. Chairman, so that the committee could without any delay appreciate the difference between the labeling of the product for home consumption and that intended for exportation.

It seems to me that information of this kind which is also provided in the companion section on food products is nothing more than what the consumer is entitled to have. There is no justifiable pretext that can be advanced by the manufacturer, to my mind, that disclosure of this sort should not be made, because it is his own private right.

I think that the commodities individuals of this country are going to take down their gullet, whether in the form of food or medicine, should be made known to them, if they have any curiosity about it. All that is being asked is that those who are curious, those who want to buy discriminatingly and intelligently, be given some means by the provisions of this bill whereby they can inform themselves.

Senator COPELAND. How far do you go at present in the demand for labeling and inclusion of the names of the active ingredients?

Mr. CAMPBELL. There are very few ingredients that are required to be stated under the terms of the present law. Those we discussed in connection with the previous section. They are largely the opiates. They are to be found in section 8 under "drugs", paragraph (2); in such cases as the content of alcohol, morphine, opium, cocaine, heroin, and others.

There is a provision in the bill that requires the declaration of these habit-forming narcotics, with a statement to the effect that they are habit forming. That is to be found in this same section, section 8, in a previous paragraph, paragraph (b), page 10.

Senator COPELAND. Let me ask you, Mr. Campbell, if you do not think the public would be sufficiently protected if the manufacturer were required to file with the Department a formula of the remedy to be placed upon the market?

Mr. CAMPBELL. I do not.

Senator COPELAND. Your thought about that is, and you expressed it very well, that a man who indulges in self-medication, who stands in the position of being his own physician, is entitled to know what it is—I think you said "putting it down his gullet".

Mr. CAMPBELL. Prescribing for himself, I think is better language.

Senator COPELAND. I went through this war once before when I was commissioner of health of New York City. I assume it must have been a compromise, but it was written into the law that it should be the duty of every manufacturer, and so forth, before offering any such medicine to be sold in the city to register the same and secure a certificate of registration from the department of health. It was our theory at the time that in that way we would know whether there were any incompatibles in the formula or any poisons in the formula; and, likewise, we would be possessed of information so that when we made seizures we would have on file in the office the material to determine that the contemporary package conformed to the formula as presented. But your view, I take it, is that that is not sufficient?

Mr. CAMPBELL. I think not. There is an advantage unquestionably in a requirement of that sort for enforcement operations, but there is no advantage accruing to the public in such circumstances. The point that I am trying to make is that each individual purchaser of this product who is to use it in the treatment of ills which the individual has diagnosed for himself is entitled to know what is the nature of the product that he or she is prescribing for that disease.

Senator COPELAND. In order that the record may show the answer, What advantage to the public is it to know that a bottle contains such articles as are designated on this bottle here? What would those names mean to the average purchaser of dope, whatever it is?

Mr. CAMPBELL. That question has arisen repeatedly in connection with this particular paragraph. I grant you that at the present time the public, perhaps generally, would not know the significance of such products. They would not know the therapeutic action of a number of ingredients that might be declared on the label; but there is no reason in the world why the public should not be given through governmental agencies the sort of information that would permit them to acquire and apply that knowledge in the course of time. But what I am stressing particularly is the importance to individuals who have hypersensitiveness to certain drug products of avoiding articles which contain such ingredients. That is of immediate importance and benefit.

Senator COPELAND. I notice in connection with "Swamp Root", which is made in my State, that while the package carries a label giving the names of the ingredients it does not give the quantities.

Mr. CAMPBELL. No. I said that was an observance in part of the requirements of this paragraph. That is a qualitative declaration. Our prosposal is to make that a quantitative declaration.

So far as the contention may be advanced that this is a property right on the part of the manufacturer, and that he should not be

required to disclose it, I think the statement made by the Supreme Court in *Corn Products Refining Co.* v. *Eddy* (249 U.S. 427) disposes of that argument once and for all. The Supreme Court said:

> It is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrets as to his compounds and processes must be held subject to the right of the State in the exercise of its police power and in the promotion of fair dealing to require that the nature of the product be fairly set forth.

The concluding portion of this particular paragraph, Mr. Chairman, gives to the Secretary the authority to prescribe by regulation such further requirements in the way of disclosure of information on the label as may be deemed necessary for the protection of public health.

Without wasting any time in the discussion of that, let me refer to this particular occurrence. The Department brought action under the Food and Drugs Act against a treatment for asthma, known as "Dr. Herman's Asthma and Hayfever Medicine." The Government lost the case. After the presentation of the evidence the jury returned a verdict to the effect that they found for the claimant; but they did the most unusual thing of including a further recommendation for the future conduct of the manufacturer.

It so happens that one of the most important ingredients in the product is potassium iodide. You know what the effect of potassium iodide is. That product is, as the physicians say, contraindicated in cases of active or dormant tuberculosis; and it was shown quite conclusively by the testimony that the use of that particular medicine for an individual suffering from hay fever and who was also suffering from tuberculosis would do immeasurable damage. The jury in connection with its verdict stated:

> We recommend that the claimant insert in his literature a warning against its use by persons having tubercular tendencies.

That is merely an illustration of the utter impossibility without provisions similar to those in this bill, to give to the public adequate information and the protection that is requisite for the maintenance of health.

It seems to me that this particular paragraph and others represent an improvement over the present law, and they represent those things that the consumer from the standpoint of avoidance of fraud or in the protection of health can expect and demand as his right.

Senator COPELAND. Mr. Campbell, let me ask you another question, for the sake of the record. Would your views be met reasonably well if it were required that the label should carry the names of the substances or the ingredients used in the order of their medicinal or physiological predominance?

Mr. CAMPBELL. Now could you determine the order of their medicinal or physiological predominance? That would not relate, would it, to the proportion in which they would be found in the entire mixture, bearing in mind that some drugs are of great activity physiologically and others only slightly so?

It seemed to us in drafting this bill that adequate information could be conveyed only by the requirement on the label of a quantitative declaration of the ingredients; and in this respect this section differs from the corresponding section under "foods."

Shall I proceed to the next paragraph?

The CHAIRMAN. I would like to ask you one question. I think in the early part of your statement you said it might be conceded that one manufacturer had a superior method of combining his ingredients of his preparation. Did you say something like that?

Mr. CAMPBELL. I think that is true in a great many instances.

The CHAIRMAN. If they were conceded to have that superior method, would it be fair to the man having the superior method for preparation to disclose to the public the ingredients of his package when the maker of the inferior product might carry upon his package the identical ingredients as to quantity and identity found in the first package?

Mr. CAMPBELL. If there is any merit in the contention that there is a definite improvement in the product due to the factory technique of one manufacturer being superior over another, then that will be very definitely recognized and appraised by the public; that will represent good will to the manufacture of the superior goods.

The CHAIRMAN. Are you not giving the public more acute powers of observation than the public possesses?

Mr. CAMPBELL. If it is not true there is not much to it in any event. If it is true that there is an advantage in the alleged secret processes by which these admixtures are combined and effected, such secret processes of course would not have to be disclosed.

The CHAIRMAN. Under the bill, in its form as proposed, would the maker of this superior article be permitted to call attention to the superiority of his method?

Mr. CAMPBELL. Why, certainly. There could be absolutely no objection to a declaration of any truthful character by a manufacturer which that manufacturer might wish to make.

The CHAIRMAN. I think that is all I wanted to know on that.

Mr. CAMPBELL. It has been frequently alleged that if manufacturers are faced with these requirements and restrictions on drug products it will discourage progress; that no manufacturer will want to spend considerable sums of money on research; for it will avail him nothing if he makes known to his competitors the results of his researches and thereby enables them to reap profits in equal measure. I know very well that our patent laws have protected industrial operations where science and research are the foundations of progress. If there is any new discovery which is developed in the course of such work, is there any reason why adequate protection in the same way cannot be accorded here as it is accorded in other lines?

Paragraph (f). This refers to package and labeling requirements imposed by the text of the United States Pharmacopœia and National Formulary. In the United States Pharmacopœia there are certain specifications now given as precautionery measures for the preservation of health in storing and using certain products. One of these is in connection with bichloride of mercury tablets. The United States Pharmacopœia monograph on this product says:

> Tablets of an angular shape having the word "poison" and the skull and crossbone design distinctly stamped upon it. The tablets are to be colored blue. They are to be dispensed in securely stoppered glass containers on the exterior of which is placed a red label bearing the word "poison".

And so forth.

That precaution manifestly is for the preservation of health, and it was to avoid fatalities which too frequently have occurred accidentally through the use of bichloride of mercury tablets. There is no provision in the existing law which can compel the observance of these requirements of the United States Pharmacopœia. Section (f) is merely an implementing provision, made to put into effect such exactions as the Pharmacopœia may impose upon the packaging and labeling of official products.

Paragraph (g) refers to deterioration. It authorizes the Secretary, after notice and hearing, to establish regulations which will first indicate such products as may have been determined to be subject to deterioration, and prescribe the circumstances and conditions under which they may be sold.

The CHAIRMAN. Is that new?

Mr. CAMPBELL. Yes, and the foregoing paragraph is.

The CHAIRMAN. It speaks for itself, that particular section?

Mr. CAMPBELL. Yes. You are aware of the fact that no such regulation now exists, and such products as digitalis, aconite, and ergot will soon deteriorate.

Paragraph (h) is the slack-pack requirement applied to drugs, as a previous section applied to food. Here is a container of castor oil. We have substituted, of course, this colored liquid so the deceptive nature of the bottle can be seen. Castor oil heightens the deception because of its colorless appearance. When you look from this angle and see how thick the two sides of this bottle are, and the small space left between them to carry the oil, you can get some appreciation of the scope of the deception.

Paragraph (i) likewise is new. It refers to drug specialties which perhaps have been more extensively exploited than any other line of drug products, germicides, bactericides, disinfectants, and antiseptics.

The public has been led to believe, by the type of advertising similar to that I am now submitting to you, that these alleged germicides constitute effective treatment for every imaginable disease. The one that I am looking at gives a display of a cross section of a human face, throat, down through the trachea, into the lung cavity. The advertisement says nothing whatever about the import of this design, but gives an extensive dissertation on the causes of various diseases and the importance of avoiding or destroying germs by the use of this particular product.

The statements in very few instances, considered independently of other statements in the advertising, can be alleged to be false. I showed you an advertisement a moment ago in which the word "tuberculosis" appeared across the top of the page. The only conclusion that could be reached by one uninitiated and reading that statement is that that particular antiseptic and germicide was of importance in the treatment of tuberculosis or in preventing tuberculosis. The value of it, Mr. Chairman, as a physician, you know is extremely limited in such instances. The inference, no doubt, will create a confidence in, and inspire a reliance upon, this product. Perhaps this may be responsible for the neglect or disuse of those conventional methods, particularly sterilization, which are now employed for prevention of infection. Certainly a large number of the diseases from which we suffer at the present time are due to different types of bacterial infection. In this particular advertisement the list

of diseases mentioned includes: Influenza, measles, pneumonia, smallpox, tuberculosis, chicken pox, diphtheria, and erysipelas.

The scope of the advertisement in its entirety, and it is true of the others, is to create a belief on the part of the readers of it that treatment for such diseases can be effectively undertaken by the purchaser of such products without further regard for medical or sanitary care.

We have found in our attempt at the regulation of such products, that some of them which claimed to be germicidal actually had germs living in them. There is no legal standard by which we can determine the germicidal strength a product should possess before it can be sold as a germicide. There is no provision that gives us power to establish standards for germicides or antiseptics. We have taken the extremely tenuous position and tried to maintain it, that no product which does not possess the power of destroying such organisms as staphylocus aurens should be permitted to be sold as germicidal. This is one of the pus forming organisms as you know. We have found and we do know that there are a number of germicides which will be effective in the destruction of that particular organism but will not have the effect of satisfactorily destroying or preventing the growth of organisms less resistant. In other words, what might be found to be a good germicide for one particular kind of germ would not, necessarily, be a good germicide for another. All that we are asking in this particular paragraph of the act is that something fairly definite be given to the prospective buyer in the way of information. If it is found, and certainly the manufacturer has the possibility of making that determination and it should be expected of him to do so, that the product is bactericidal or germicidal toward a certain organism only, then let him sell it under a label which declares it to be that and which indicates the conditions of use, the length of time, and the necessary concentrations. If he does not wish to do that and insists upon labeling it as a germicide unqualified then place upon him the obligation of making a germicide for all types of vegetable micro-organisms and justify the confidence which he desires, and which will be placed in it under such circumstances—namely, that it is an effective general germicide.

The CHAIRMAN. Have you the facilities of enforcing this particular provision? How would you do it?

Mr. CAMPBELL. There would be a difficulty always in determining what would be the effect of a product in a human body. The only facilities which exist now for making that determination are those of the laboratory. But if we were to find that a germicide which claimed to be such for some type of micro-organism would not in fact kill that organism in any period of time, in any concentration, certainly we would have adequate reason to say in that case that the sale of that product as a germicide was deceiving and defrauding the public. It is granted that there is a difference between the determination of a germicide in vivo and in vitreo. There is a difference between laboratory determination and effect on the human being. The fact that these products cannot be used effectively in combating diseases, particularly when the germs themselves have lodged in that portion of the anatomy where they cannot be reached, and where, if a successful germicide were employed, destruction of the body tissue would result, ought to be a sufficient argument against them. Perhaps this paragraph should be made even more stringent. The

purpose of it is to curb or restrict the license now enjoyed by manufacturers of such articles.

Section 9 is the one relating to advertising.

The CHAIRMAN. I dare say there is some dispute about this.

Mr. CAMPBELL. I do not know of any question that has raised such a storm, or of any other item in any other section of this bill about which there will be such dispute. I understand that there will be reflected in the statements made before this committee at these hearings the opposition that exists in certain groups. It reflects the possible and probable effect of the bill in limiting the exploitation of the public by the sale of harmful and worthless nostrums to those who would, perhaps, buy amulets just as readily. The degree of opposition that will become evident may perhaps exceed that which has manifested itself heretofore. Do not think for a moment that this section will not be objected to. I do not believe that any restriction could be imposed upon the patent-medicine business without provoking the advancement of every kind of opposition. We do not have to go far to determine the reason. Even in a time of depression that has been a flourishing industry. Certainly, in normal times it was a very flourishing industry, and equally certainly it will continue to be, so long as its stock in trade is the exploitation of the public by appealing to their superstitions, fears, and emotions. Unquestionably, this proposal will be opposed by patent-medicine makers and people of that class. No provision that seeks to prohibit the patent-medicine manufacturer from deceiving and defrauding the public will be unopposed. No provision that seeks to compel the patent-medicine manufacturer to let the public know something of the truth about his product will be passed without the keenest opposition. When they take the public into their confidence, as they will to some extent through the elimination of false representations, the inherent worthlessness of many of their products will become known. This is the type of information that the public will acquire.

May I say at the outset that the proposal to include, in this bill, provisions which would cover advertising of food and drug products did not contemplate and does not now contemplate censorship in the sense in which this term is ordinarily used. It contemplates setting up no bureaucrat in the Department, no single individual, not even the President of the United States, to determine with finality whether advertising is or is not true. What it does do is to enjoin the use of false advertising in the sale of food, drug, and cosmetic products. There is nothing vicious in that, or unnecessarily or unfairly restrictive. It makes no difference to what extent Congress may go to compel by law the use only of truthful statements on labels of such products, you will not have protected the public unless these provisions are extended to advertising. It was stated by Representative Sabath at the time the Sherley amendment was before Congress, that the value of that amendment would be slight to the public and that no amendment that contemplated the curtailment of unlimited fantastic deceptive declarations on labels would be of any practical value unless the same curtailment were extended to advertising. We have patent-medicine frauds with us now just as definitely as we have ever had, the variation being only in degree. What has been done has been to transfer in large measure the field of activity for

making false claims. The label is no longer employed so effectively for that purpose. The labels of food products are frequently meaningless, utterly without any statement or information, of an informative or deceiving kind. The advertising is dictated by just what the manufacturers wish to have it say. There are no restrictions placed upon it. The proposal now is to extend to advertising some of the beneficient provisions, from the public standpoint of the present law. Whether the advertisement is or is not false will be determined in every instance by the court.

The claim has been repeatedly made that it will be utterly impossible for advertising activity to continue, that it will mean the loss of hundreds of employees; that products cannot be put on the market; that the harshness of the language now employed and the use of the words "ambiguity" and "inference" will make it impossible for the manufacturer to prepare an advertisement without putting himself in a position to be promptly sent to jail; that no manufacturer will advertise under such circumstances. It has been said that the combination of this particular section, the definition of misbranding and the definition of adulteration of drugs, is extreme, harsh, and so vague as to be utterly unreasonable; that together they are unsound both in principle and in policy.

Those are extravagant statements. The only thing that is required to meet the terms of this section is that the manufacturer, in having his advertisements prepared, take the same precautions to be consistent with the truth that is imposed upon him now in the preparation of his labels; nothing more. We know that there are advertising puffs, trade puffs. The Supreme Court recognizes that. That license cannot, however, be employed to the deception of the public. Trade puffs, to which the court has referred, do not deceive. They are those statements to which there has been built up a consumer resistence because they are recognized for what they are. The only representations that we are anxious to have eliminated from advertising, the only statements that we desire to have deleted, are those that result in the deception of the public. The protection of the public against deception is a proper part of this legislation. If it cannot be extended to advertising, the purpose of the bill, and certainly its practical effects, will fall to the ground.

Speaking about the effect of such legislation and what it would do in an industrial sense, I do not know anything better that I can do than to quote from an article prepared and published by one of the leading authorities on advertising; one that is recognized more or less generally as a leader in that field.

Exactly 22 years ago, when this particular writer, whom I shall quote and who was, I believe, then editor of the publication in which his article appeared, was advocating legal measures to suppress false and misleading advertising, he took into account the very same thing that has been very recently expressed by Hotchkiss. The latter has said that:

> There still remains a considerable proportion that is grossly exaggerated or on the border line of the unethical. It violates no statute and contains no untruths, but it nevertheless conveys false impressions. No outside authority that is now available seems capable of eliminating this shady advertising. Unless a new statute can be formulated to cover it—which seems doubtful—improvement must come by voluntary restraint on the part of advertisers.

The author recognized 22 years ago that the same type of abuses in advertising about which Hotchkiss comments in the foregoing quotation prevailed then. The same condition of which he complained prevails today.

The CHAIRMAN. How long ago was that?

Mr. CAMPBELL. Twenty-two years ago. In the concluding portion of his article the author says:

> I do not want to close this introductory paper without emphasizing the great importance of the goal. First, there are the ethical and moral considerations involved, and about those we are all agreed.
>
> Second, there is the vast benefit to be conferred upon advertising itself. If we can eliminate the dishonest, the misleading, the indecent from advertising, we will double or triple or quadruple the confidence of the public in advertising. This means that more people will read and respond to advertising than at present. It means that advertisers will get better results from advertising than they are now getting. It means a reduced cost in distribution via the advertising road. It means that space in advertising mediums will command, and will be worth higher prices. It means that the rewards for the individual worker in the advertising field will be larger. In fact, it is a matter in which we can all make common cause—advertisers, publishers, and advertising men generally, if not for ethical and moral reasons, then at least for motives of self-interest.

Advertisements are written to produce very definite effects. This is particularly emphasized in the food-and-drug line. I have heard it asserted and truly, I think, that advertisements of foods and drugs must move the products. They are written to create a very definite impression and effect in the mind of the reader. This talk about no manufacturer, under the terms of this bill, having the courage to prepare an advertisement through fear that some statement unwittingly made might inferentially deceive or mislead the reader is without merit.

Advertisements are studiously prepared to create an impression on the reader and a demand for a product. These advertisements should be prepared with a full sense of obligation on the part of the writer of them that he should be truthful in every statement, and should not ambiguously or inferentially make any statement of any character which will deceive or mislead.

I know of no great authority that I can cite to maintain that it is possible, that it is practicable, and, in fact, easy to prepare advertisements that will not mislead and deceive, than the Supreme Court of the United States. I refer to the case of the *United States* v. *95 Barrels*, more or less, alleged apple cider vinegar, Douglas Packing Co., claimant, 265 U.S. 438, where it is said:

> The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act. The statute applies to food, and the ingredients and substances contained therein. It was enacted to enable purchasers to buy food for what it really is.

The CHAIRMAN. Did you give a citation of that?

Mr. CAMPBELL. Yes, sir; I gave it. Our purpose is to insist that in advertising there be an element of honesty, which has not extensively characterized a large proportion of this business in the past.

Senator MCNARY. If a newspaper should publish an advertisement from which an inference might flow that the contents do not have values therein stated, what would happen to the newspaper man?

Mr. CAMPBELL. Nothing, under the provisions of this bill. You will find in section 17 a list of penalties. If you will look on page 24, line 19, you will find the specific language exempting publications. Let me say as a prelude to the quotation of this language that the drafters of this measure fully realize that publishers cannot readily determine the truth about food and drug products. It is impracticable for them to maintain laboratories and a corps of experts to make analyses and decide with respect to a particular advertisement whether statements contained in it are true or false. There are some publications that attempt to do so in a measure, but to expect them to do it completely and exactly is out of the question. The responsibility in this matter ought to be put on the individual who has knowledge of the things he is advertising, and that is the manufacturer himself. That was contemplated in paragraph (d) of section 17, which reads:

> No person acting in the capacity of publisher, advertising agency, or radio broadcast licensee shall be prosecuted under paragraphs (b) or (c) of this section for disseminating a false advertisement if, on request of an officer or employee duly designated by the Secretary, he furnishes the name and post-office address of the person who contracted for or caused him to disseminate such advertisement.

Senator, the suggestion has been made that this exemption is a joker; that the department, if it wished to institute prosecution against a publisher, could do it very simply. In other words, if it were the purpose of the Department to institute a prosecution against a publisher, it could do so by resorting to the expedient of not having a representative request the name and address of the responsible party. The Assistant Secretary of Agriculture and others have disavowed that intent, and have stated that they are perfectly willing to see this language made more certain so that there can be no possibility of it operating in that way. I am suggesting, in line 20, on page 24, that the word "if" be eliminated and that the word "unless" substituted, and on line 21, the word "furnishes" be deleted, and that the words "refuses to furnish" be substituted so that that sentence will read:

> No person acting in the capacity of publisher, advertising agency, or radio broadcast licensee shall be prosecuted under paragraphs (b) or (c) of this section for disseminating a false advertisement unless, on request of an officer or employee duly designated by the Secretary, he refuses to furnish the name and post-office address of the person who contracted for or caused him to disseminate such advertisement.

Senator MCNARY. Doctor, I just want to get your view regarding the interpretation of section 9. If the newspaper publisher should advertise certain values involved in a certain patent medicine and one individual who bought a bottle of it felt they had created a misleading impression, would that individual have a separate action against the newspaper?

Mr. CAMPBELL. No.

Senator MCNARY. What does that mean, then? Is that an individual or a group?

Mr. CAMPBELL. Perhaps by careful investigation you could find an individual who would be unable to understand a statement written in the plainest and most specific terms. I cannot conceive that any misleading impression which would be reached by a person so incapable of interpreting the English language would constitute a basis upon which court action could be inaugurated. This section, like the present misbranding section of the food and drugs act, would be enforced by undertaking to determine what would be the inference or conclusion to be reached by a reasonably intelligent person or people from that language. I think that was the attitude the Supreme Court had in mind in rendering the opinion to which I referred. Administrative officers must first reach a conclusion on the question. We would consider totally unreliable the testimony of an individual who definitely misinterpreted a specific and accurate statement.

Senator MCNARY. Would your department attempt to decide whether the ad appeared to be misunderstood?

Mr. CAMPBELL. It would be required to do so in the first instance. Quite naturally it must reach a conclusion that the ad is false and misleading before it could take the steps indicated in this bill to refer the matter to the courts on a charge that it is false and misleading.

Senator MCNARY. Does the Department decide whether there is any misleading language or not?

Mr. CAMPBELL. The Department decides it, but the Department must assume in every case to sustain by adequate evidence that its findings in that respect are correct.

Senator MCNARY. By evidence tending to prove that that had been misleading and false?

Mr. CAMPBELL. Yes, a number of witnesses. It would not be possible to try it on one isolated instance.

Senator MCNARY. The point is if it is inferred. This is a thing that is not easy to understand. Why do you say "by ambiguity or inference create a misleading impression"? What is the reason you go beyond untruth? You must first establish the untruth of the article.

Mr. CAMPBELL. Yes.

Senator MCNARY. Why do you use the words "ambiguity" or "inference creating a misleading impression"?

Mr. CAMPBELL. That is indeed a pertinent question, Senator, and I hope to explain it by referring to the advertisement I showed you a moment ago, with the word "tuberculosis" across the top of the page. I said when presenting it that I did not think there was perhaps a single sentence in it that could be considered positively untrue —speaking of the individual sentences.

However, I think that the inference to be drawn from the entire advertisement is so obvious that few would hesitate to consider it false. That is the sort of misleading advertisement covered by this language.

The CHAIRMAN. I think you can use language which would be better if you had it read "or is capable of creating a misleading impression."

Mr. CAMPBELL. If I may explain briefly, Senator, our purpose in using that language was to employ the most explicit terms possible in writing the definition. That is made possible by using the language of the Supreme Court in interpreting the existing terms of the act defining misbranding. As I pointed out to you, in the present law it says that the product is misbranded——

The CHAIRMAN. You are referring to page 18?

Mr. CAMPBELL. Page 17, section 8:

> That the term "misbranded" as used herein shall apply to all drugs or articles of food or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein, which shall be false or misleading in any particular.

Now, in interpreting the last four words the Supreme Court has said in the decision to which I referred that deception may result from inference and ambiguity. It is possible to state the truth and still create a false impression by an advertisement of the kind to which I have referred, such an advertisement may be read by taking every sentence in and of itself, independently, severally, and divorced from the rest of the article, and found to be entirely true; but there can be no question in anyone's mind about the final conclusion which will be reached. As I have said, in using this language, we have merely paraphrased the requirements which now exist in the present definition of misbranding.

You may ask, most properly, why we did not use the language in the present law; as a matter of fact, we would be satisfied to have misbranding and false advertising in the bill defined in that language.

Our thought was that if the bill carries in specific words the interpretation of that language, as expressed by the Supreme Court, it will apprise manufacturers more completely of their responsibility.

The CHAIRMAN. You are seeking merely to relieve any misunderstanding of the law, as those provisions of the law have already been interpreted?

Mr. CAMPBELL. Yes.

This particularly refers to ambiguity and to inference and is, as we interpret it, through the medium of the Supreme Court decision, nothing more than is required right now of statements on labels.

The CHAIRMAN. Would there be any objection to inserting the word "material" on line 22?

Mr. CAMPBELL. What page?

The CHAIRMAN. Page 12, line 22:

"Shall be deemed to be false if in any material particular it is"——

Mr. CAMPBELL. If you add any other words like "material" then you have introduced——

The CHAIRMAN. Another lawsuit?

Mr. CAMPBELL. Another lawsuit.

With greater vagueness of meaning, it will cause more difficulty.

If you make it less exacting than the labeling provision of the present law, the value of the prohibition would be greatly diminished. I do not think we would be getting the result we are after here.

If the requirements of the present law can be met insofar as statements on labels are concerned, why can we not apply it with the same force and effect to advertisements?

The CHAIRMAN. Let me ask you a further question: If section 8, line 17, of the existing law, if that were interpreted in the light of the decision which you quoted, you would be entirely satisfied?

Mr. CAMPBELL. Yes; that is quite right. That is all we are asking for.

As a matter of fact, we could have perhaps allayed some of the apprehension that has been developed in the public consideration of this bill if the language now existing in the present act had been employed in the bill, and there had been no effort on our part to do what seemed of advantage to the manufacturers by giving them a clear view of their obligations under the law.

The CHAIRMAN. If you had left the old language in, you would have saved me a lot of headaches.

Mr. CAMPBELL. If I were inclined to take headaches from this criticism, I would have been suffering most of the time.

The CHAIRMAN. You have no objection to Dr. Emerson's suggestion that "contemporary" be put before "medical opinion"?

Mr. CAMPBELL. Not at all. I think that is an improvement.

The CHAIRMAN. Go ahead.

Mr. CAMPBELL. In (c), the first few lines introduce the purpose of this paragraph more effectively than anything that I might say to explain it. It says that to discourage the public advertisement for sale in interstate commerce of drugs for diseases wherein self-medication may be especially dangerous, or patently contrary to the interests of public health, any advertisement of a drug representing it indirectly, or by ambiguity, or inference, to have any effect in the treatment of any of the following diseases shall be deemed to be false. Then follows a list of such diseases.

The CHAIRMAN. Suppose on line 13 you inserted the word "curative." Would you be willing to say that there is no medicine that would affect something in the way of adding comfort or palliation to diseases listed there?

Mr. CAMPBELL. This applies to advertising only.

There are certain diseases where it may be contrary to the interests of society to have a self-diagnosis and self-treatment undertaken.

To discourage the tendency on the part of victims of those diseases, to further impair their health, reaching the point where, perhaps, even through the administration of the conventional treatment, recovery would be made impossible, our thought was to proscribe absolutely any rerefence in advertisements to such diseases, whether the statement made describes it as a cure, a palliative, or anything else.

The CHAIRMAN. On line 17, that is manifestly an error; a typographical error.

Mr. CAMPBELL. Yes.

The CHAIRMAN. That was written perhaps by an Englishman; was it not?

Mr. CAMPBELL. Perhaps so.

Let me draw your attention now particularly to the statement beginning on line 22:

> Except that no advertisements shall be deemed to be false under this paragraph if it is disseminated to members of the medical and pharmacological profession only, or appears in scientific periodicals.

There is no disposition to write anything into the bill to interfere with progress. If, in the course of time there should be developed therapeutic agencies, or adjuncts which are effective in the treatment of these various diseases, of course, it would be in the interests of society to have them placed on the market.

The advertisement statement which may mention these diseases and may be made in scientific publications to be read, not by laymen but by those who have definite knowledge of the causes of diseases and the limitations of medical treatment, must in every instance be as definitely true as the advertisements that appear in lay publications.

The proviso on page 14 is one which authorizes the subtraction from this list, and the following proviso is one that authorizes additions to the list.

Exemption in scientific periodicals does not, as has been asserted, lift the ban on truthfulness.

That concludes this section

We have already discussed section 10, I think.

We have also discussed section 11.

The CHAIRMAN. Mr. Campbell, I would like to have you return to the second proviso on page 14.

Mr. CAMPBELL. Line 14.

The CHAIRMAN. "That this paragraph shall not be construed as indicating that self-medication for diseases other than those named herein or designated by regulations of the Secretary under the authority hereof is safe or efficacious."

Is that a little bit gratuitous?

Mr. CAMPBELL. Yes. That is wholly gratuitous. The only purpose was to prevent the conclusion being reached inadvertently that the foregoing portions of this section did subscribe to the principle that self-medication for diseases other than those listed herein was advantageous.

The CHAIRMAN. That is the usual province of the physicians?

But, it seems to me, just a bit strange to put it into the law.

However, it is not worth arguing over now.

Mr. CAMPBELL. Section 12 is the one that authorizes the Secretary to require manufacturers of certain classes of foods and drugs, or cosmetics, to obtain licenses. It has been asserted that this would be a requirement generally imposed.

There is no such purpose involved in suggesting that section, and the very terms of this section would prevent such use being made of it.

It speaks clearly, and says that only in those instances where products are injurious to health, and furthermore where such injurious nature cannot be adequately determined after they have entered interstate commerce, is the Secretary authorized after notice and hearing, to make such regulations governing the condition of manufacture, processing, or packing, as he deems necessary to protect the public health.

Our prime motive was to protect the public against occurrences like the botulinus out breaks some years ago from the consumption of ripe olives. There were many fatalities.

Botulinus infection comes from the soil, and it is necessary to insure proper handling of food products in order to avoid it.

Perhaps the olive industry at that time could not have been blamed altogether for what occurred.

And, I wish to state that the condition has been quite definitely corrected.

The packing of olives is now so directed and supervised to eliminate very largely the conditions which would cause a recurrence of botulinus infection.

That was done by California agencies working out a very definite method of processing, which renders the product safe.

The organism is one which they realized that they had to contend with at all times. The germ which causes botulism comes from the soil, and it is very extensively distributed. It is the toxin produced by this organism which causes illness and death.

The packing operations, for these and for other food products—I refer now to olives—are at present carried on under all conceivable precautions and conform to methods which it has finally been determined, will make the food product safe for consumption.

The precautionary steps taken in the interest of the consumer have proved effective.

It is our expectation that this section will be employed with infrequency and only when as experience has shown the protection of the public health cannot be otherwise assured.

It is not contemplated that the license system shall be imposed upon the general line of manufacturers of foods, drugs, and cosmetics. It will be employed only where dangerous outbreaks occur, or dangerous products are produced, and where there can be no correction otherwise.

The CHAIRMAN. It has been suggested to me that there will be a very general imposition of this system, because it might be such as to demand or sufficient to cover an inspector hired constantly in the factory; was there any such thing in the thought of the Department?

Mr. CAMPBELL. Not at all.

Senator COPELAND. You are simply aiming here to take care of special problems, like that of the olive?

Mr. CAMPBELL. That is right. These permits are temporary; they will be issued only temporarily. Where a condition is found that involves a menace to health, and it can be corrected, it is the purpose to prevent shipping of the product from that plant until corrections have been made. The following paragraph (b), merely refers to the revocation and the renewal of these permits, dependent upon developments, as they manifest themselves from time to time. Paragraph (c) merely authorizes access to the premises at appropriate times by the inspector. This quite naturally is necessary in dealing with the serious condition which is to be expected where this authority is invoked, and is requisite for satisfactory handling. Are there any more questions on that, Mr. Chairman?

Senator COPELAND. I am glad that you have made the statement with respect to your idea of a permit, namely, that the permit is to be used only in the case of emergency involving the public health.

Mr. CAMPBELL. That is right.

Senator COPELAND. And it has nothing to do at any time with those products which could in no sense undermine health.

Mr. CAMPBELL. Not at all. I think the terms of the section itself are very definite, and that they impose their own limitations.

Senator COPELAND. All right. Go ahead.

Mr. CAMPBELL. Next is section 13.

Senator MCNARY. Is that wholly new?

Mr. CAMPBELL. Section 13 is entirely new. This authorizes an inspection of manufacturing plants, warehouses, or establishments in which foods, drugs, and cosmetics are manufactured and which are held for shipment in interstate commerce. This is merely an

implementing section, Mr. Chairman, and is essential for the effective protection of the public. Ordinarily, most manufacturers readily permit an inspection of their plants, but there are some that do not. Most warehouses readily permit it, but there are some that do not. It is in those cases where that permission is not granted, that it is necessary to adopt some provision of this sort for effective control.

Senator COPELAND. Under the police power of the Senate, the health commissioner, or the inspector of the health department, could go into any factory, as a rule.

Mr. CAMPBELL. Yes, ordinarily. Most of them have statutory authority that will permit them to do it, but we have this situation right now; there are shipments of food stored in certain warehouses and our previous investigations have indicated that they are of a character which will impair health. The State official in this instance is not permitted to enter; we are not permitted to enter. The result is that proper protection of the public imposes upon us the necessity of establishing a sort of picket or guard which will be available at all times to apprehend shipments when and as they enter interstate commerce.

As another illustration of the need of this section, a vinegar manufacturer can make distilled vinegar, can color it, and under direction of expert control, can produce a product which will give all of the chemical reactions of genuine cider vinegar. There is no way, however, by which the control chemist and authorities charged with the responsibility of seeing that that imposition does not occur can acquire the facts upon which appropriate action can be based.

Senator COPELAND. In short, if the owner gives permission, of course the inspector goes in.

Mr. CAMPBELL. That is right.

Senator COPELAND. But if the owner refuses consent, then application can be made to the court?

Mr. CAMPBELL. That is right.

Senator COPELAND. There the reasonableness of the proposition, or the reasons for the application, will be considered?

Mr. CAMPBELL. Quite right.

Senator COPELAND. And decision made according to the merits of the case?

Mr. CAMPBELL. Yes.

Senator COPELAND. Proceed, please.

Mr. CAMPBELL. Section 15 is substantially what is in the law now. This authorizes the Secretary to make investigations, and authorizes State health, food and drug officials to report their findings to the United States attorneys for action. It is merely in modified form, but substantially what is in the law at the present time.

Senator COPELAND. That is all in section 15 that you are referring to now?

Mr. CAMPBELL. Yes. Paragraph (c) is likewise essentially what is in the act at the present time, except that the term "interested parties" found in line 6 of page 20, is new language. The law at the present time requires the Secretary, before the institution of criminal prosecutions, to issue citation to the party from whom the sample was obtained, that is, usually, the dealer. The responsible party, the one who should be accorded an opportunity to appear to show cause why prosecution should not be instituted, is the manufacturer. As

a matter of fact, under administrative operations, and by regulations now, we are doing that without the requirement of law. We are asking for this legislative confirmation of an existing administrative practice.

Section 16 refers to seizures. The first paragraph contains the same authorization carried in existing law, with the exception of those modifications necessary to accommodate the prior provisions in this bill. They do not in any sense modify the authority which now exists.

There is a new provision in this section, to be found in item 2, under (a), line 24, which authorizes the chief of the station or other officer of the Food and Drug Administration designated by the Secretary to effect the seizure of immenently dangerous products.

Senator COPELAND. And it is in that case only that you can proceed?

Mr. CAMPBELL. It is in that case only that we can proceed.

Really, I do not think that there would be occasion for invoking that authority once in years, but when such authority is needed, as in some of the botulison outbreaks, and with shipment perhaps unwittingly of other products capable of causing this definite harm—when that occurs, it is important that the apprehension be made at once.

Senator COPELAND. Would you have any objection to the insertion, in line 3, after word "then" of the words "in such case only"?

Mr. CAMPBELL. Not at all. There is no necessity for making any comment on the following paragraph. Next we come to section 17, on page 23, penalties. The penalty section is almost in its entirety, new, and, quite naturally, it makes provision for much greater penalties than are carried by the present law.

The present statute makes manufacturing of an adulterated or misbranded food product in the District of Columbia or any Territory an offense for which a fine of $500 and 1 year's imprisonment can be imposed for the first offense, and not less than $1,000 and 1 year's imprisonment for the second offense, but that is only for the District of Columbia or a Territory.

The penalties of the present law applied to the ordinary case of interstate shipment of goods throughout the country authorized a fine not to exceed $200 for the first offense, and $300 or 1 year's imprisonment for the second offense. These penalties are so ridiculously small that they are in a practical way disregarded.

Senator COPELAND. Mr. Campbell, you say that this section is almost all new. You mean that it is all new as regards the increased penalties? You have penalties under the present law.

Mr. CAMPBELL. Yes.

Senator COPELAND. If this should become effective, what would be the practice of the Department? Suppose that a concern had been found to be operating in violation of law, would there be an immediate action brought against that concern, or would they be brought in for private reproof, or warning, and so forth?

Mr. CAMPBELL. There would be an immediate action brought against him, either against him or his product. We have found it necessary, because of the smallness of these penalties, frequently, for adequate protection of the public, to develop an unusually large number of seizure actions. And, furthermore, we have done this: Wherever we could get evidence of a conspiracy to violate the law,

we have brought prosecutions under the conspiracy section of the criminal code. The penalties are greater.

We concluded, some few months ago, the trial of an important case in Brooklyn, N.Y. That was the case of a ring of bootleggers responsible for the preparation of spurious jamaica ginger containing a poisonous ingredient, and resulting in extensive outbreaks of paralysis among consumers of the product. If we had brought prosecutions, under the Food and Drugs Act, against the manufacturers and shippers of that product, they would have escaped with a fine of $200 or less, since it was the first offense against them.

We spent virtually a year and a half working up the circumstantial evidence, and because we were able to show that there was a conspiracy to violate this law they were given jail sentences, which they are at the present time serving.

Senator COPELAND. I go as far as any man with respect to any law which has to do with the protection of public health, but I wondered, where there might be technical violations by perhaps not willful perpetrators, but perhaps innocent violations by the manufacturers, if private reproof should not be the first step that should be used, before he is hailed into court.

Mr. CAMPBELL. Such violations have undoubtedly occurred in the past, and will occur again. There may be no intent involved in the commission of the offense in such instances. Most usually the offense is committed without deliberate motive, or frequently that is the case, I know, too, that there are a great many instances where direction of the manufacturer's attention to the practice is sufficient to effect correction.

I have no brief to hold in such circumstances for the imposition of unduly severe penalties; but in the preparation of a law that contemplates dealing not only with that person, but with those who are actuated by entirely different motives, you can scarcely make a legislative discrimination.

Let me say, furthermore, that the existence of more severe penalties will make the manufacturer more conscious of his obligations to the consumer, more careful in the preparation of food and drug products for others. There should be an effort on his part to see that there is an observance of that meticulous care, necessary to prevent any misbranding or any form of adulteration.

Now, the penalty is very much more severe in the case of willful offenses than it is for offenses committed in the manner you have suggested.

Senator COPELAND. Where is that pointed out?

Mr. CAMPBELL. That is paragraph (c) on page 24, in line 12, which reads:

> Notwithstanding the provisions of paragraph (b) of this section, in case of a willful offense, the penalty shall be imprisonment for not less than 6 months nor more than 3 years, or a fine of not less than $1,000 nor more than $10,000, or both such imprisonment and fine.

The next section refers to liability of corporate officers.

The first paragraph of that, paragraph (a), substantially is what is in the act at the present time, and that is to the effect that the act of an agent or an employee of a corporation shall also be taken to be the act of the corporation.

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Senator COPELAND. Let me ask you, with respect to that material on page 25; is not practically all of that in the present law?

Mr. CAMPBELL. The guaranty section is practically identical with the present law. All of that material which refers to penalties, Senator, is different from the terms of the present law. That is the remedial section of this bill.

Paragraph (b) of section 18, of course, is a corollary to the foregoing paragraph, and states that where offenses have been committed under the direction of individual directors or officers or agents of the corporation, they shall be jointly liable with the corporation.

The next section, section 19, to my mind is one of the most important sections in the act. It provides for the suppression of repetitious offenses. In the present circumstances there is no way by which that can be done effectively. If an article is misbranded or adulterated, the manufacturer can continue for a protracted period its production and shipment in interstate commerce because of the delay incident to the conclusion of a prosecution. Even though a conviction were obtained, it would be impossible to bring the matter at issue to a definite determination without the lapse of an inordinate period. This section by expediting action and suppressing continued offenses is for the more adequate protection of the public, and permits the consideration of the whole question on an equitable basis, because proceedings under it would be instituted in courts of equity.

The import section is in every respect what we have now, that is, in substance, with a very slight change in some portions of the language of it.

Section 21, publicity, on page 28, is an extension of the existing authority conferred upon the Department to publish notices of judgment.

Senator COPELAND. I would like to ask you a question about this.

Mr. CAMPBELL. About section 21?

Senator COPELAND. Yes. It states:

> The Secretary shall cause to be published periodically a report summarizing all judgments, decrees, and orders which have been rendered, and all proceedings instituted and seizures made, including the nature of the charge, and the disposition thereof.

I have been wondering if it was quite fair to the manufacturer to have this product seized, and, before he has had an opportunity to have his day in court, to have publicity given to the fact that there was seizure.

Mr. CAMPBELL. Well, it is public information, Senator. The moment that this action is instituted in a court, the fact is available to the public that the goods have been apprehended.

Senator COPELAND. You are speaking about a court seizure, are you?

Mr. CAMPBELL. Yes.

Senator COPELAND. And not a seizure by one of the inspectors?

Mr. CAMPBELL. No. Do not think, because of the provision in a preceding paragraph which authorizes an inspector to make seizure in cases of emergency, that in such instance there would be no court action. That paragraph does authorize an immediate apprehension of the goods, but then it also requires immediate action to place those goods in the custody of the court.

Senator COPELAND. What is your practice now as regards publicity of the action on the part of the Department?

Mr. CAMPBELL. The present law authorizes the Department to publish notices of judgment. They consist of a brief statement of the offense and the decisions rendered by the courts. Notices of judgments are published as governmental publications. That is the extent of publicity by governmental publications, other than as it may be carried in the annual reports.

But I have done this: I have inaugurated a practice, as a matter of information to the public, and to enable it to acquire knowledge of the scope of the work being done by the Food and Drug Administration, of giving out statements in the nature of press releases once a month summarizing the operations of that month. The extent to which publicity is given to that statement, of course, is something over which I have no control. I am inclined to think that it receives only slight publicity.

Senator COPELAND. To pursue the matter a little bit further, of course if there were a seizure involving court procedure, that would of necessity be known to the public?

Mr. CAMPBELL. Yes.

Senator COPELAND. In other words, this publicity that you are speaking of would not be new, and would not be gratuitous on the part of the Department.

Mr. CAMPBELL. Not at all. It is something that the public could acquire, and something that the public ought to know. This, of course, goes further than that, and says—

> The Secretary shall cause to be published periodically a report summarizing all judgments, decrees, and orders which have been rendered, and all proceedings instituted and seizures made, including the nature of the charge, and the disposition thereof,

and

> The Secretary shall cause to be disseminated such information regarding any food, drug, or cosmetic deemed necessary in the interest of public health and for the protection of the consumer against fraud.

If we had that power now, and cosmetics were subject to the law, we would immediately publish to the four corners of the country the deleterious effects that are likely to be produced from the use of the cosmetic, Lash-Lure. We had no authority, as I told you this morning, to take action under the law, against Radithor, the water-containing radium salts, but we did, through the medium of press releases, issue warnings from time to time about such radium products. If we had the authority indicated here, we could publish the effect of the distribution of such warnings.

Dr. Emerson has discussed this section on voluntary inspection service, and I agree with everything he said about it. This does not provide for as ambitious a program of action as Dr. Emerson has outlined.

In this particular section there is merely an authorization to the Secretary to render a service to the manufacturers, in the belief that it will operate to the public benefit. A service of this type is rendered now under the item in the appropriation bill to which I referred previously. If the manufacturers want it, our purpose was to create authority for the Secretary by which they could acquire it. I am holding no brief for the section, and I am not disposed unduly to urge it.

The next is general administrative provisions. Here the Secretary of Agriculture is authorized to prescribe such regulations as he may

deem necessary for the efficient enforcement of the functions vested in him by the provisions of this act, including regulations with the force and effect of law as to notice and conduct of hearings, by the Secretary. Then the paragraph provides that he and the Secretary of the Treasury shall promulgate jointly such regulations as relate to the control of the imports of foods, drugs, and cosmetics.

Paragraph (b) authorizes, by reference, the exercise of the powers conferred upon the Federal Trade Commission by sections 9 and 10 of the Federal Trade Commission Act, and, incidentally, title 49 is a misprint.

Senator COPELAND. Where is that?

Mr. CAMPBELL. That is on page 30, line 21.

Senator COPELAND. What is the mistake?

Mr. CAMPBELL. That is title 15, I think. I am sure it is.

Senator COPELAND. The Federal Trade Commission is undertaking to carry out what you have in mind, but for lack of appropriations or because the function is not placed with the right department, not much progress has been made, and I am wondering if that is what you have in mind?

Mr. CAMPBELL. We have in mind this: In various sections of the bill the Secretary has been authorized to establish tolerances by regulations, to make certain findings of fact; in these operations it is important, in order that no injustice may be done, that he have available the most complete information. Under the powers conferred upon him by sections 9 and 10 of the Federal Trade Commission Act, he could require production of records which might be necessary for an intelligent discharge of his duties in this respect.

Now, perhaps the provision that has caused most misunderstanding is that portion of this section covered by paragraph (c), that "hearings authorized or required by this act shall be conducted by the Secretary or such other officer or employee as he may designate for the purpose. The findings of fact by the Secretary shall be conclusive if in accordance with the law."

There is ample precedent in various Federal statutes of recent date for delegating to the Secretary of Agriculture, or some other administrative officer, the powers that have been delegated in this section and in previous sections. Some of the statutes are the Clayton Act, the Federal Trade Commission Act, the Longshoremen's and Harbor Workers' Compensation Act, the Packers' and Stockyards Act, the Grain Futures Act, the United States Grain Standards Act, and the Tariff Act. Furthermore, authority to make findings and regulations having the force and effect of law are conferred upon the Secretary by the McNary-Mapes amendment to the existing Food and Drugs Act.

Instead of having innumerable provisions set forth in the terms of the law itself, on the question of tolerances, for example, it seems to me that it would be more equitable and would operate for the greater protection of the public to authorize the current administrative determination of these questions which are inevitably of a shifting character.

This practice, Mr. Chairman, has been established and is recognized as constitutional by the courts. In Union Bridge Co. against the United States, (204 U.S. 387) the Supreme Court said:

> Indeed, it is not too much to say that the denial to Congress of the right under the Constitution to delegate power to determine some fact or the state of things upon which the enforcement of its enactment depends would be to stop the wheels of the Government in the conduct of public business.

There are several cases here supporting that general idea, which I will not take up your time to read, but the widespread misapprehension which undoubtedly prevails about the consequences of the final paragraph of this section is probably the association of it with section 15 (c). You will note that in the procedure to be followed by administrative officers in the institution of prosecutions, that paragraph says that the Secretary shall, before reporting any violation of this act to the United States attorney for the institution of criminal proceeding, afford due notice and opportunity for hearing to interested parties in accordance with such regulations as the Secretary shall prescribe. Here the Secretary is according to the prospective defendant a chance to discuss his case and present reasons, if he can, why it should not be carried to court.

That sort of hearing is one of an entirely different character from those required of the Secretary, in the determination of facts incident to the establishment of tolerances, the establishment of standards of identity and quality. It is the latter hearings and findings of fact following them to which this particular section refers.

In order to avoid misunderstanding, I suggest that the word "the" in line 2 be eliminated, and the sentence modified to read: "In formulating regulations, findings of fact by the Secretary shall be conclusive if in accordance with law."

Senator COPELAND. I think that is a very helpful suggestion.

Mr. CAMPBELL. There was some discussion this morning, and I am not sure that it was not left in such form as perhaps to create some misunderstanding about the tolerances for poisons established by the Secretary under the power conferred in section 10 and this section.

Regulations establishing tolerances would have the effect of law. All required of the Government to prosecute for violation in such cases would be to show that the poisonous ingredient was in excess of the tolerance established by the Secretary for that product. Regulations establishing food standards would have the effect of law, quite as definitely as the legislative standard for butter at the present time, which requires that there be as much as 80 percent butterfat. There would be no appeal from such finding.

That does not mean, however, that there could be no court review of that finding. At the present moment the Department of Agriculture is under injunction from the exercise of the authority conferred by the McNary-Mapes amendment. The standard promulgated by the Secretary under the terms of that act was not agreeable to a manufacturer packing dry peas, in a way which we concluded was in contravention of the standard. By injunction he has prevented further action against him either in the form of seizure or of criminal prosecution until a court review of the departmental standard occurs.

So, while there would be no appeal from the Secretary's findings, there would always be available adequate court review at the instance of someone who undertook to establish the fact that the findings were capriciously and arbitrarily made without supporting evidence.

I do not know, Mr. Chairman, that there is anything further.

Senator COPELAND. Let me ask you about section 24, on page 31. Is that a little gratuitous?

Mr. CAMPBELL. That is a statement of legal rights.

Senator COPELAND. They have that power now, if they will ever get it?

Mr. CAMPBELL. Right.

May I make this further statement? To summarize briefly the features of this bill, it undertakes by its terms to regulate interstate traffic in cosmetics, for reasons which are obvious; it prevents false advertising; it forbids the sale of drugs which are harmful under the prescribed conditions of use; it makes self-medication safe by preventing medicines from being sold as cures, unless they are cures; it requires habit-forming drugs to bear warning labels, and makes sheer ignorance no longer a valid defense for highly exaggerated claims.

It outlaws poisonous foods, whether the poisons be normal or added; it provides tolerances for, and prohibition of added deleterious ingredients; authorizes promulgation of legal standards for foods and compels reasonable standards of cleanliness in the production and handling of foods.

The bill insists on labels being truthful, and requires that they carry sufficient information to permit intelligent buying.

In the interest of public health, it authorizes the secretary under certain conditions, to license manufacturers, it provides for a voluntary inspection at the option of the manufacturer.

The bill increases penalties, and provides, in cases of imminent danger, for executive seizures; it enjoins repetitious offenses.

These are all new provisions to be added to the statute as it is now. We realize that, even with these additions, the law will not be a perfect one. We are conscious of its limitations. There will doubtless be criticism of it because it does not go far enough to guarantee public protection; certainly there are those who will criticize it for going further than they wish. It does manifest progress. It will make it possible for the Government to extend greater protection to the public than is now the case.

It will not create a single condition to give justifiably undue apprehension or concern to honest manufacturers. There is no requirement here that cannot be met by them without undue expense or unreasonable inconvenience. In asking these things for the consuming public no concessions are sought. They are demanded as a right. To authorize them, is, we think, the payment of a debt long overdue.

[Applause.]

Senator COPELAND. Mr. Campbell, you are entitled to the applause you received. Your address today has been remarkable in many ways. You have made clear and distinct, and in a temperate manner, the reasons why there should be greater control over food, drugs, and cosmetics.

We are going on a little while longer, but not long. We have heard only one side of this matter today, and I am told that there are persons here in opposition, and I shall call first Dr. J. H. Beal, of the Drug Trade Conference.

Mr. FRAILEY. Mr. Chairman, may I make this introductory remark?

Senator COPELAND. You may, Mr. Frailey.

STATEMENT OF MR. CARSON P. FRAILEY, PRESIDENT, NATIONAL DRUG TRADE CONFERENCE

Mr. FRAILEY. I am appearing here today as President of the National Drug Trade Conference. The Drug Trade Conference is a delegate body, composed of nine national associations representing the various branches of pharmacy in the drug trade.

The conference met in annual convention day before yesterday and adopted, among other deliberations, a resolution, which reads:

Whereas the development of advertising methods since the adoption of the Federal Food and Drugs Act of June 30, 1906, has resulted in abuses which that act now fails to adequately control, and

Whereas the elimination of the false or fraudulent advertising of medicinal products is essential to the proper protection of the public health, the safeguarding of which is recognized by this organization as paramount to commercial or other considerations; therefore, be it

Resolved, by the National Drug Trade Conference in annual convention assembled, That a committee be appointed by the Chair to prepare one or more bills to provide for such amendment of the Federal Food and Drugs Act and if necessary for such amendment of other Federal Statutes as will make them completely effective for the control of the false and fradulent advertising of medicinal products, whether disseminated in connection with such medicinal products or otherwise, and also that the said committee shall draft such other amendments to existing Federal Statutes as in its opinion may be necessary to prevent the distribution of dangerous cosmetic preparations in interstate commerce and also to prevent the false or fraudulent advertising of such cosmetic preparations, and be it further

Resolved, That said committee be authorized to offer such bill or bills for enactment by the United States Congress either as original bills or as substitutes for measures now pending in the Congress; and be it also

Resolved, That said committee be authorized to tender to any representatives of the Federal Government the assistance and cooperation of the National Drug Trade Conference and of its individual members in the preparation of amendments to any of the laws relating to and control and regulation of the advertising and distribution of drugs, medicines and cosmetics in interstate commerce.

Mr. FRAILEY. In pursuance of that resolution, the Chair appointed a committee, of which Dr. James H. Beal is chairman.

Dr. Beal is one of the outstanding leaders in pharmacy. He has been identified with all of the important laws, State and National, relating to drugs for the past 35 years.

He drafted the first model narcotic bill ever prepared in this country, and much of that draft became a part of our Harrison Narcotic Law, which the National Drug Trade Conference helped to enact.

He therefore has accumulated an experience which, in my opinion, is unequaled by any other man in that field in this country, and I ask you, Mr. Chairman, to hear at this time Dr. Beal on behalf of the National Drug Trade Conference.

Senator COPELAND. There can be no doubt of the eminence of Dr. Beal, and I am glad to welcome him as a witness before the committee.

STATEMENT OF DR. JAMES H. BEAL, REPRESENTING THE NATIONAL DRUG TRADE CONFERENCE

Dr. BEAL. There is a historic connection between the representation of our association here and what has gone before.

Perhaps I should start by telling you that the first public meeting to consider the formulation and the enactment of laws to control

adulterated and misbranded drugs was held in the city of New York in October 1851. This public convention consisted of the various apothecaries, as we called them then, resident in New York and Philadelphia, and the members of the teaching faculties of the New York College of Pharmacy and the Philadelphia College of Pharmacy.

The primary purpose of that convention was to take into consideration the then very imperfect state of the laws controlling the importation of adulterated and sophisticated drugs.

Before that convention adjourned, it resolved itself into an association known as the American Pharmaceutical Association, which is one of the Associations which I have the honor to represent.

This is the association which has very lately completed a beautiful building in a portion of Washington next to the Lincoln monument.

The interest of our Association in pure food and drug laws has been constant, and a part of our annual program. Every poison law in effect in any one of the individual States first appeared in the papers and reports of the American Pharmaceutical Association, and every prohibition of a narcotic or habit-forming drug which has appeared in the United States was first formulated under the auspices of the association, and the text of the Harrison Anti-Narcotic Law, as it was adopted by Congress, was formulated by a committee of the National Drug Trade Conference, which requested its introduction by Senator Harrison, and which finally became what you now know as the Harrison Anti-Narcotic Law.

So that naturally, as a result of this history, the profession of pharmacy, as represented by the American Pharmaceutical Association, and also of the Drug Trade Conference, as represented by the National Conference, or the National Drug Trade Conference, are very deeply interested in any class of legislation which attempts to change materially the fundamental character of the existing food and drug legislation.

The basic theory of the present food and drug act, adopted June 30, 1906, was that articles of food and drugs should be what they purported to be, that is, that the labels of such drugs must be truthful, that in no case shall they be false and fraudulent, and that the pruchaser, or the citizen having the truthful statement on the label before him, shall be permitted to decide for himself whether or not he will purchase such product.

With that as its basic theory, the Federal act of June 30, 1906, went into effect with probably a greater degree of success than any other statute ever placed upon the Federal statute books.

Prior to that time, the standards of drugs and medicines in the United States were a reproach to the citizens of this country. Today we have the highest, and not only the highest theoretical, but the highest actual standards on foods and drugs of any nation, and I make this statement deliberately knowing exactly what it means, and am prepared to substantiate it.

This is not merely an American opinion. Let me call your attention to the fact that a few years ago a selected committee on the House of Commons of the British Parliament was appointed to consider a drug legislation, and that after a prolonged investigation of all the drug laws of the civilized world, they took back to their parent body a report in which the statement is made that the American Food and Drugs Act is the most efficient act of its kind in existence.

Senator COPELAND. That is a great tribute to America.

Dr. BEAL. And they are not accustomed over there to pay tributes of that kind unless there is a real foundation for it.

Now, this new measure which we have before us is not merely a correction of possible existing defects in the present law, or even a general revision if its terms. It amounts in effect to an entire rewriting of the law, introducing new principles and to a large extent changing the basic theory of the law. For the free choice of the consumer, based upon a truthful label, is substituted the principle that citizens are to have not what they want, but only such things as the Secretary of Agriculture believes may be good for them.

Probably the most noteworthy feature of this new bill is the enormous, perfectly enormous extent of the discretionary power which would be conferred upon the Secretary of Agriculture. As written, the bill might be considered as sort of a skeleton statute, having a certain number of fixed points, established by the Congress of the United States, but leaving great gaps which must be filled up with Bureau definitions and regulations.

Now, it is an established principle that a defendant cannot plead a misunderstanding of the law as an excuse for its violation, but it is equally fundamental that the law shall be so specific in its terms that the citizen, through the exercise of reasonable diligence, may be able to ascertain the extent of his obligations thereunder.

But if this bill is enacted as written, the producer of medicinals could not determine the extent of his obligations from the text of the law, but would be governed by regulations issued by the Secretary of Agriculture, regulations extending and changing statutes at will, and giving to its provisions such particular modifications as, from time to time, the Secretary believes they should have.

If the regulation today is one thing, the manufacturer has a certain obligation which he must perform, or suffer the consequences. Tomorrow the Secretary of Agriculture may change that obligation, so that he is released from the act which was criminal yesterday, and a new one is imposed instead.

Now, one vastly important point to bear in mind is that the enactment of the bill proposed here, Senate Bill 1944, will mean the practical nullification of the mass of decisions and interpretations accumulated through the 27 years of enforcement of the existing law.

Another equally important fact is that it will necessitate corresponding enactments in the 48 different States of the Union, so that the drug trade can be assured of a period of turmoil almost constantly for the next 5 or 10 years.

Now, it is the opinion of many who have devoted careful study to the subject that the present Food and Drugs Act does not need entire revision, but merely an extension of its terms to cover present day requirements. The same provisions which have effectively driven false and fraudulent labels from the market will, when properly extended, be equally effective in exterminating false and fraudulent advertising, and in controlling the distribution of dangerous cosmetics.

Now, we admit that as the law at present exists, there are some blanks which it fails to cover; we not only admit that, we assert it. In our association programs we have been asserting it for a number of years, and we have been proposing what we believe to be adequate remedies.

When the Federal Food and Drugs Act was enacted, Mr. Chairman, the most glaring defect which we had to meet in those days was the one which dealt with the label on the outside of the carton, and somehow or other those of us interested in the formulation of that law were so impressed by that fact that we lost sight of everything else. Later, when an amendment to this act was passed, we did get fairly good control over the face of the label, whether appearing on the bottle or on the outside of the package, or carton.

As I say, we concede certain material defects in the present law, and we are anxious to see them corrected, and we stand ready to assist to the extent of our ability to see that they are corrected.

Now, it is all well enough to say that a certain bill has certain admirable general principles. Whether or not those principles will be carefully carried out, so as to accomplish their true purpose, or whether it will fail to accomplish that purpose, and result in possibly greater evils, depends upon the specific provisions by which the principles are attempted to be put in force.

Now, Mr. Chairman, on behalf of my association, I wish to call your attention to some provisions which seem to us to be defective. You will be responsible—your committee—for the final text in which this bill is put by the national legislative body—if it should ever get that far.

In section 2, dealing with definitions, I wish to call your attention to the effect upon the definition of "drugs" after introducing the word "devices," and the word "devices" is introduced there without any qualifying or limiting terms.

Now, we concede that there are medical devices which are falsely and fraudulently advertised and sold, and we concede that this abuse should be corrected, but we wish that you would, in finally passing upon the text of this bill, consider the possible effect of this term "devices" as it now stands.

Under the new definition, the term "drug" will include such multifarious items as trusses, suspensories and obesity bandages, shoulder braces, fountain syringes and contraceptives, tooth brushes, spectacles and eye glasses, ear trumpets, and artificial aids to hearing, artificial teeth and limbs, gymnasium equipment, and so forth.

Now, since this also applies to animals as well as to man, it includes check reins, to make horses hold their heads up, interference pads, to prevent them from interfering, blinkers, to prevent them from exercising the function of their eyes to the right or left, and dog muzzles [laughter]—all of these could, if the definition were not limited by proper qualifying terms, be construed to the mitigation or prevention of disease intended to affect the functions of the body of man or other animals.

We come now to section IV, relating to the adulteration of drugs.

Senator COPELAND. Are you going to recommend some change of language?

Dr. BEAL. I am going to call attention at this time, Mr. Chairman, to what we believe to be improper statements in the bill.

At a later date we hope to be able to recommend some language which we believe will cover the question.

Senator COPELAND. Do you not think that that would really be more helpful than the line of attack that you are taking?

Dr. BEAL. If the Senator will concede me the opportunity of continuing so as to get through as quickly as possible, I will attempt to answer any questions later. Paragraph (a) provides that a drug shall be deemed to be adulterated "if it is or may be dangerous to health under the conditions of use prescribed in the labeling thereof."

Now, since the phrase "may be dangerous to health" is undefined in the bill, it follows that its limitations must be supplied by regulations, which means that the quality and quantity of danger will be measured by the opinion of those who frame the regulations.

Now, it is a matter of common knowledge that there are occasional individuals who are supersensitive to the action of certain drugs and foods to even such ordinarily innocuous substances as the white of an egg, milk and strawberries, which will set up very serious reactions, and, unfortunately, these cases of hypersusceptibility cannot be determined in advance. We only find out the people who are susceptible when the drug is actually administered or actually applied in practice in daily life.

Unfortunately, such cases of hypersusceptibility can be discovered only through the actual use or application of the particular agent.

Under the bill as written, if applied literally, almost any known drug could be excluded from interstate commerce. The language should, therefore, be modified either by some limitation of the phrase "may be dangerous to health" or by an express exception showing that occasional cases of allergy and idiosyncrasy are not included within the law.

Senator COPELAND. Mr. Campbell, is this new language?

Mr. CAMPBELL. That is new language.

Senator COPELAND. And also (V)?

Mr. CAMPBELL. (V) is not new language.

Dr. BEAL. (V) is largely the same language.

Senator COPELAND. Go ahead, Doctor.

Dr. BEAL. Paragraph (b) of section 4 provides that U.S.P. and N.F. drugs will correspond to U.S.P. and N.F. standards. This is not exactly what it is in the main.

An expansion of the corresponding paragraph in the existing law, and down to line 13, is unobjectionable, except perhaps for the inclusion of the indefinite and unlimited word "formula" in line 10.

This word "formula" is one which has more than one significance in the Pharmacopœia and pharmacy generally.

Do we understand that the word "formula" as here used applies to the symbolic or graphic formula of a drug of definite chemical constitution, or does it refer to the working formula or process by which the article is produced?

That should be made clear here.

Senator COPELAND. Do you suggest the language?

Dr. BEAL. No, sir. My suggestion would be to strike it out.

Senator COPELAND. You mean the word "formula"?

Dr. BEAL. I would strike it out as unnecessary, as adding nothing whatsoever to the merits of the bill.

Senator COPELAND. If I understand you, you would strike out the word "formula" altogether?

Dr. BEAL. Yes, for this reason, that the working formulas or processes of the Pharmacopœia are constructed for the purpose of being operated upon the small scale, the making of 1, 2, 3, or 4

pints of a mixture at a time, and these small formulas which work so well in these small scales will in many cases not work at all in the large scale, in the large manufacturing laboratory, such as we have in Philadelphia or Baltimore. They cannot use those formulas.

Senator COPELAND. Why is that? Because you cannot mix up a big batch as well as a smaller one?

Dr. BEAL. That is one of the reasons. Take in the case of percolation, where you might get a very satisfactory percolation in a percolator holding two litres. It would not work at all if you had to use the same method of packing and the same period of maceration and other corresponding manipulations where you percolated 5,000 or 10,000 pounds.

What we contend is that what is important is not the particular working process by which the product is produced, but the product in its finished state, ready for dissemination in interstate commerce.

So that word "formula" should either be stricken from line 10, or clarified by definition to show that it does not refer to the working formula or process of manufacture.

The exception introduced in lines 14 to 18, authorizing a departure from the tests or methods of assay of the Pharmacopœia and National Formulary and the substitution of quite different tests, appears to be a dangerous innovation.

Under the bill as written the manufacturer is compelled to conform to the tests prescribed by the U.S.P. and N.F. or be subject to prosecution for shipment of adulterated drugs in interstate commerce.

But, having complied with the official tests and methods of assay, and having shipped his goods into every State in the Union, they may all be made illegal by reason of the fact that an administrative officer chooses to discard the officially prescribed tests and to substitute others of his own.

As I say, by regulation, the Secretary of Agriculture can set aside the U.S.P. and prescribe an entirely different set of tests.

Senator COPELAND. If I remember correctly, Mr. Campbell said that now there are continual sessions of the Pharmacopœia Committee, and that a subcommittee is permitted to set up new standards, which are accepted by him, and become a part of the Pharmacopœia.

Dr. BEAL. Usually what we call supplements.

Senator COPELAND. Yes, but in case that system should be done away with, it might happen that in the 10-year period that there should be a considerable change by reason of scientific advance.

Is that what you had in mind, Mr. Campbell?

Mr. CAMPBELL. It was. I stated to you at the time it was under consideration that I thought there would be only infrequent occasions in which this particular authority would be invoked, that there was at the present time authority granted to the revision committee to effect ad interim revisions of the Pharmacopœia, a grant which had not characterized certain of the other Pharmacopœia editions, and since the Pharmacopœia meets only once in 10 years, it is important at least from a regulatory control standpoint, that the methods of assay which undertake to establish the integrity of the drug be sufficiently accurate to do that. From time to time methods become obsolete, as we acquire more information about more precise methods which will disclose some form of sophistication.

So it is of the utmost importance, not only to the consuming public, and the user of the drugs, but to the honest manufacturer of drugs, that the integrity of these products may be established in an efficient and up-to-date manner. The only thing that we want to do is to make more effective the control of drugs where there has been found to be a deficiency in the methods that exist at the moment. We assume that there will be cooperation between the revision committee of the Pharmacopœia Association and the Food and Drug Administration, or any other Federal or State organization that may be concerned in this matter. I think that in most instances it will be sufficient to call to the attention of the revision committee the fact that improved methods have been worked out and that they should be employed for the more effective guaranty of the purity of the product.

Senator COPELAND. Excuse my having broken in, Doctor, but that is the way I understood it. That is what the Department had in mind in using this particular language.

Dr. BEAL. That undoubtedly was the intention of the regulation. Nevertheless, Mr. Chairman, as it stands, it constitutes what seems to be a potent danger to the interests of the legitimate manufacturing pharmacists.

We further believe it to be unnecessary. While it is true that in the United States the Pharmacopœia meets as a whole only once in 10 years, the revision committee is in session 365 days in the year throughout the entire 10 years, and the board of trustees is active every day and every week of the year.

The revision committee has authority to prepare these supplements as rapidly as new developments in pharmacy and chemistry are created or come into existence, and as rapidly as those supplements are prepared they can be published and are published by the board of trustees.

Senator COPELAND. Is it not your judgment that it would be unlikely that the Department of Agriculture would at any time assume to go over the action of the Pharmacopœia committee?

Dr. BEAL. All of the abuses that have been introduced into the law have been introduced either under the excuse that they had a beneficent purpose or would not be abused, and we are simply pointing that out here as a provision which delegates power that can be improperly exercised—not that I have the slightest feeling that my good friend Campbell would intentionally ever exercise power unlawfully or arbitrarily, but since we are called upon to state our ideas on the text of this bill we think it our duty to present these facts.

Now, we think some of these things in the bill were introduced through inadvertence. Others were introduced because of the fact that those who were responsible for the particular language did not possess the practical and technical information necessary to express themselves properly. Nobody need tell me that this is not a professor's bill; I can tell that by reading it. I have been a university professor myself for 40 years or more, and I know the breed. I know how they express themselves.

Senator COPELAND. I have been a professor, too, and I want to say that I did not write this particular language. I would be willing to have it omitted from the bill, and I am anxious to be shown at the proper time why it should be left in.

Dr. BEAL. Thank you.

Under paragraph (d) of section 4 a drug will be deemed to be adulterated "if any substance has been mixed or packed therewith so as to reduce its quality or strength or when (2) if any substance has been substituted wholly or in part therefor."

Now, here is a fault which I think is purely inadvertent, merely an oversight on the part of the framers of the bill—and I may say that we chased these people all over Washington for a period of weeks trying to get into contact with them to assist them in the preparation of the text of this measure, and we never succeeded in catching up with them or in establishing a practical contact, and as they did not give us the opportunity, we are expressing what we have to say about it now.

Now, nature rarely or never produces alkaloidal vegetable drugs of the exact strength prescribed in the Pharmacopœia. Sometimes they are deficient in the percentage of active or potent constituent; and sometimes they contain an excessive quantity.

Take, for example, the standard strength of opium. There the only thing that we can do in order to secure accuracy of dosage is to try to assay the opium, and if it is too weak, to add stronger, or if it is too concentrated, to add some weaker opium, until we ultimately get what we should, a final drug of exactly 10 percent.

Pharmacopœia making has three models which are fundamental. The first is accuracy, the second more accuracy, and third the most complete or possibly complete degree of accuracy, and that is why we have to modify these drugs from time to time, so as to get just one particular strength, no other.

So our suggestion, Senator, is that the word "injuriously" should be inserted before the word "reduce" so as to make the line read: "injuriously reduce its quality or strength."

Senator COPELAND. Just a minute before you leave that, Dr. Beal. I do not get quite the same meaning out of that paragraph that you do. If any substance has been mixed or packed with it so as to reduce injuriously or injuriously reduce its quality or strength, that does not mean that you are going to put the same substance in it.

I have in mind putting sawdust in, or something or other cheaper than the regular product.

Dr. BEAL. That would not make any difference, because while we would not use sawdust, there are better things than sawdust, such as sugar of milk.

That paragraph, as I read it, means this, if it were applied literally and unintelligently, and it can be shown that we had reduced the strength of opium from 14 to 10 percent by the addition of sugar of cream, or, not opium, but take some other preparation, it would be illegal under this phrase, as it now stands, in the bill; its percentage strength must be reduced in order to make it a proper Pharmacopoeia substance, and therefore we are asking for the legal authority to reduce its crude natural strength to the requisite standard.

Section 5 deals with the adulteration of cosmetics. That has only a very indirect interest to our organization, or the organizations now represented in the National Drug Trade Conference, although the apothecary inventor first introduced perfumes and cosmetics, and we have Holy Writ as our authority, for you will recall the formula for the manufacture of an aromatic substance or perfume which was to

be made according to the art of the apothecary. Some of our people manufacture these, and many of them, especially the retailer, sell cosmetics, and we just want to call your attention to the fact that the powers conferred here are in very general terms. There is not set forth a list of the dangerous drugs which ought to be interdicted.

We are agree that they should be interdicted, and are willing to do what we can to interdict them.

It does not prescribe the lines of legal authority within which the Secretary of Agriculture must operate, within which his regulations may be effected. It turns the whole subject over to him without let or interference, and, so far as the language of the text is concerned, he can declare anything on earth as an improper ingredient in a cosmetic.

Remember that some dermatologists have gone so far as to declare in very emphatic language that the application to the skin of such harmless substances as talcum, starch, or bland fatty oils, are injurious to the user, and it might be that some day there may be someone in the Drug Administration who might subscribe to that particular idea and exercise that power, so that now we are simply calling your attention to this blanket authority without any restriction or limitation, and we wish you to consider in your wisdom as to whether or not that should be permitted to stand.

Senator COPELAND. But you are not giving us any language yourself to help us in the matter.

Dr. BEAL. We are proposing, with your permission, at a later date to submit one or more drafts embodying these various suggestions.

In other words, I start out with this premise, that the present Food and Drugs Act, which has operated so efficiently and is faulty only because of later developments, can be made effective in destroying every one of these abuses, about which we all know and some of which have been presented to us today.

The reason that it has not been as effective in controlling advertising matter inside the carton and surrounding the package is because its terms were not extended to that. We did not understand that when we wrote the original law. Human nature is like a toy balloon; you squeeze it in one place and it expands somewhere else. We pretty effectively controlled the falsehoods on the actual labels, but they simply expanded their falsehoods into the newspapers and the circular matter which accompanies the package.

Senator COPELAND. I take it that your view about this particular thing is that you want to take into consideation the average person, and you want to get some elasticity, so that where there is supersensitivity, that it will not be counted against the manufacturer.

Am I right in that?

Dr. BEAL. Yes, sir; as relating to the section that I just referred to.

If I may continue, I wish to call your attention to section 6, misbranding, general provisions.

Paragraph (a) of section 6 provides that a food, drug or cosmetic shall be deemed to be misbranded—

"If its labeling is in any particular false, or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetics."

That is beautiful language; fine language, and to a layman it seems to be perfectly clear, but when we examine it from the viewpoint of its practical application to the labeling of drugs, it is highly ambiguous,

and liable to lead to many misleading interpretations and unwarranted inferences.

Senator COPELAND. Suppose that we were to take the present law as interpreted by the court decisions: Would you have any objection to that language?

Dr. BEAL. Not the slightest. Many of the expressions in here are practically the same as those in the existing food and drugs act. They are not dangerous there. Why? Because all of the parts of the act must be construed together and the dangerous possibilities in one provision are properly cared for by safety provisions, but here in this new act we find a whole host of new provisions not hitherto tried in this or any other country, so far as I know.

We are afraid; we are scared; we do not know what is going to happen; but we do know what has happened in certain parallel instances where unlimited power has been placed in the hands of an executive.

We might not always be fortunate enough to have Judge Campbell in the Food and Drugs Bureau, or Franklin Roosevelt in the White House; and the proper way to control the power is to limit it when it is granted, so it cannot be abused.

Senator COPELAND. I am in the fullest accord with that statement.

As applied to drugs, this language fails to distinguish between falsity or fact which can be proved by material evidence and falsity of opinion which in many cases can neither be proved nor disproved.

The language is ambiguous for the reason that it is based upon the theory that one of the most uncertain and indefinite of subjects—the description of the therapeutic application of drugs—can be subjected to the same rigid rules of interpretation as can be applied to problems in physics and inorganic chemistry.

In the latter cases, when the factual data are established, the reactions can be predicted with certainty and accuracy, whereas the therapeutic valuation of drugs must always be largely a matter of opinion.

Judged according to the leading authorities of the so-called "regular school of medicine", the claims of eclectic and homeopathic physicians as to the virtues of their peculiar remedies are false, while eclectics and homeopaths hold the same opinion as to many of the remedies employed by the regulars.

Then along comes the osteopath, who says that the beliefs of the whole outfit are false and mistaken. [Laughter.]

Not only do the various schools of medicine differ in their valuation of remedies, but physicians of the same school are frequently at variance in their estimation of the same agents, and if a large number of textbooks on therapeutics are compared, scarcely any two of them will be found to be in complete agreement as to the therapeutic usefulness of identical drugs.

Because of these uncertainties, it follows the evident effect of this language would be to make the opinion of the Secretary of Agriculture the standard for the determination of falsity, ambiguity, and misleading inferences. You might place before him all of the material that we have, and if he puts his hand on one of them and says: "This is the authority that we accept", then he has himself fixed the standard of falsehood, ambiguity and misleading impressions.

I will now pass to section VIII—misbranding of drugs.

The first sentence of paragraph (a) of section VIII provides that a drug shall be deemed to be misbranded—

> if its labeling bears the name of any disease for which the drug is not a specific cure, but is a palliative, and fails to bear in juxtaposition which such names and in letters of the same size and prominence a statement that the drug is not a cure for such a disease.

I think it is too bad that the people who drafted this language did not call somebody in who knew something about the meaning of these terms before they were included in this paragraph.

This language is radically defective, in that it includes various terms of very indefinite and uncertain meaning, and which therefore should never be used in punitive statute without the addition of limiting definitions.

The term "disease", "specific cure", and "palliative" do not possess any exact and definite meaning in law, in medical science, or in the English language, as set forth in generally accepted dictionaries.

Take the word, "disease." I examined a leading medical dictionary under the term "disease." It gave three or four general definitions, no two of which corresponded to each other, and then there followed with a column and a half of special definitions of "disease", according to the manner in which it was applied.

The combination "specific cure", is rarely employed in medicine, though the word "specific" is used with various meanings.

Though usage is not entirely uniform, the tendency is to employ the word "specific" when unqualified by other words, as the designation of an agent capable of destroying or preventing the reproduction of organisms, which are the cause of certain well defined diseases.

In this sense, quinine alkaloid is a specific for malaria, arsphenamine a specific for syphilis, and the number of drugs which can be truly termed specific in this sense is limited by the number of diseases known to be caused by the number of specific organisms.

As applied to eclectic medicines, which are also extensively employed by physicians of the so-called regular school, the word "specific" is used in the sense of special or particular, meaning that the remedy is specially or particularly adapted for use in the treatment of named affections without intending to imply that they are certain and complete cures therefor.

As applied to the specific medicines of homeopathic physicians, the adjective has a meaning somewhat similar to but not entirely identical with the sense in which it is empoyed by the eclectics.

The word "palliative", though not capable of so many different interpretations, has the terms "disease" and "specific cure", and is nevertheless far too indefinite for inclusion in statutory law without limiting definitions. It might be interpreted as a merely soothing application to a painful part, as a remedy which alleviated the symptoms without affecting the course of the affection; as an agent which, although not a complete cure, is nevertheless appropriate in the treatment of a stated ailment.

I have referred to homeopathic medicines. I know some people smile when I mention homeopathic medicines and physicians, but I have been connected in one capacity or another with the pharmacy and drug business since the third day of July 1876, and I have had

an opportunity to see a number of various homeopathic physicians, and I do know of some very remarkable cures being effected by homeopathic medicines, after the medicines applied by the regulars had apparently failed.

So, Mr. Chairman, we think that this language either should be limited by the proper application of definitions, or stricken from the bill entirely, and we call your attention to the fact that under this section as written, the same drug may be legal if we adopt one set of interpretations of these various works, or illegal if we adopt another.

Now the particular sense which is going to be applied is going to be that of the Secretary of Agriculture, or his designated official. It may be true that we may proceed into court and ask that these rulings be set aside, but remember that we do not pass laws with the understanding that they are to be in such a condition that we will have to go to a court to have them nullified in order to secure justice.

Senator COPELAND. May I ask, Doctor, if you regard this as better or worse language, if this labeling bears the name of any disease in the treatment of which the drug is not generally accepted as the specific?

Dr. BEAL. If that word "specific" would be omitted, not generally accepted as an appropriate part of the treatment, that would go a long way toward curing it. If that word "specific" is kept in there, it means that we cannot use medicines or label medicines or advertise medicines for more than half a dozen seasons.

Senator COPELAND. You are entirely right with regard to your statement, regarding the different views regarding the term "specific", but, yet, at the same time, is there a generally accepted view as to what a specific is?

It is limited, I think Mr. Campbell said here in his statement here this morning, and you repeat it, to 4, 5, or 6 diseases, and that is what Mr. Campbell had in mind.

Dr. BEAL. And those diseases are included in another section of the bill. Dr. Oliver Wendell Holmes said that if all the medicines were put into the sea, it would be better for man than for the fishes, but we are dealing with a situation where it is understood that we are going to continue to use the medicines, and do the best we can.

Senator COPELAND. After all, in formulating a bill which is intended for lay reading, as well as for reading by scientific students, we have to have language general enough and plain enough so that the wayfaring man, though a fool, need not err therein. You are more competent to judge than I am, but I believe that there is a general acceptation on the part of all schools of medicine and all students of science that there are certain specific cures, certain drugs which have a specific value, such as quinine for malaria, mercury for syphilis, and so forth. That is what I mean by saying that we could never satisfy the homeopaths, or the eclectic, when we came to any effort on our part to define the word "specific" but there is a general acceptation, nevertheless, of the meaning of the word.

Dr. BEAL. I would expect, then, that in the accompanying language of the bill it would be made perfectly clear that it was to be interpreted in that restricted meaning.

Senator COPELAND. I think you said that at a later time you were going to furnish us the language that would cover it.

Dr. BEAL. Yes; with the understanding that we are trying to build on the whole bill. Now, some of our friends have said, "Why don't you put into this bill a provision of the kind that ought to be there?" We did try it, and I confess to you that it is an absolutely impossible task for me, and the only way to make an acceptable bill out of this, which would insure fair tests to the manufacturer as well as to the public, would be to strike out everything after the enacting clause and put in the old Food and Drug Act, and make the appropriate changes in it. I am perfectly willing to have somebody write it, so that we could accept it, but I confess my own inability to do it.

The second division of paragraph (a) provides that a drug shall be deemed to be misbranded—

if its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.

What is the general agreement of medical opinion? Who knows what it is? Who knows where it can be found? I have not been able at any time during my connection of more than 50 years, more than half a century, with the practice of pharmacy, to be able to find, whenever I wanted to, what was the general agreement of medical opinion.

Take some matters entirely within your own recollection. When the Pharmacopœia was last being revised, prohibition was in its heyday, and a strong propaganda was conducted to strike whisky and brandy from the United States Pharmacopœia, and they attempted to ascertain the consensus of medical opinion upon it, taking evidence on the subject, and after vote of its members upon the question of whether or not whisky or brandy played any part in the practice of therapeutics that could not be equally well discharged by some other agents, whisky and brandy were deleted by a comparatively small vote.

Well, now, it turned out that those physicians who thought that they could find acceptable substitutes afterwards concluded that they were mistaken, and in the next Pharmacopœia of 1920—and I should have said that the other was of 1910—whisky and brandy were voted back into the Pharmacopœia as necessary medicinals of an overwhelming majority. [Laughter.]

Now, we have there the general agreement of medical opinion——

Senator COPELAND. That happens in theology, too, doesn't it?

Dr. BEAL. Yes, sir. I used to be a professor in a theological school; so I know.

Senator COPELAND. You are so versatile that you are positively dangerous, Doctor.

Dr. BEAL. Thank you. Another case. Everyone knows that liver and liver extract are today recognized as the most efficient and desirable agents in the treatment of pernicious anemia, but that has only been for a few years.

Senator COPELAND. We may not believe it next year.

Dr. BEAL. Yes. Suppose that when it was introduced, Judge Campbell would say, "You cannot get away with that here. You cannot find medical opinion in the whole United States that will sustain that. That is contrary not only to the general agreement, but the whole agreement of medical opinion, and you cannot do it."

He would have been justified. In fact, he would have been compelled under this language to execute the law in that way.

Take ipecac. That is a drug introduced many years ago as a cure for amoebic dysentary. It enjoyed a great repute for many years. In other words, it represented the general agreement of medical opinion. Then it went out of repute, and dropped clear out as a treatment for amoebic dysentary. The use of it only continued with some various homeopathic and eclectics, but it was entirely out of repute with the balance of the physicians. Then suddenly the slant turned the other way and now and for a number of years ipecac and its two alkaloids are firmly established as the most efficient agents that we have for the combatting of amoebic dysentary.

They also use malaria germs as a cure for paralysis. They will give a man malaria to cure the paralysis, and cure the malaria some other way.

Senator COPELAND. I am worrying a lot about this line 22. It is an extremely difficult thing to get a general agreement among medical men, almost as hard as it is to get a general agreement as to any legal proposition.

I have wondered about that, and have suggested at various times whether or not we might not use the language that the general agreement as to the classes resulting from scientific or clinical diseases, or something like that. I know how difficult it would be, but Mr. Campbell this morning, I think, got down to a percentage of 80. That would be a high percentage.

Dr. BEAL. Yes.

Senator COPELAND. Fifty-one percent would be high. [Laughter.]

Dr. BEAL. We are confronted with this situation, that we have no definite method of determining therapeutic value.

Now, that seems strange to the layman who has followed popular literature, and who thinks that we have some kind of a magic wand, and that we can put the drug on it, and determine whether it would be a good medicine or not, or he may have heard of animal experimentation, say with the guinea pig.

The study of the guinea pig method is limited, because some will thrive on certain things that are deadly to men, and some humans can eat the kind of foods which are deadly to guinea pigs. There is a lack of parallel action between the guinea pig and the man. When we try a drug on the guinea pig, and that is all, and if we want to know what it will do to the man, it has to be tried on the man, and doctors have been very falsely blamed for experiments on their patients.

In a sense, every administration of a dose of medicine is an experiment. Your patient is a test tube, and you put the medicine in it and test the tube and see what happens, but you are guided by the fact that the physician himself has had a long period of clinical experience; that he has behind him a record of generation after generation of physicians who employed the same drugs in the same way, who stood by the bedside and have observed the fluctuating tide of life as it responded to these different remedies. He has something to go on. But he must depend upon the clinical experience of himself and his colleagues, past and present.

I heard something today which seemed to me rather pitiful, considering the source from which it came, that we should disregard the old knowledge of medicine. Some of the most valuable knowledge that we have concerning drugs and the action of medicines on the human system runs back to the days of Hypocrates and Diascates.

Some of the most certain data that we have, some of the most standard medicines that we have in the Pharmacopoeia, have been there from the days when the first practitioners of medicine in Egypt were known and they still give results; and, as for myself, if I had my life in danger, or that of one of my friends, I would a good deal rather trust the treatment of the case to an old-fashioned doctor who has had wide acquaintance, actual experience with the treatment of patients, than to the man who has just come out of the guinea-pig laboratory, because I have stood behind the prescription counter and have filled prescriptions by the guinea-pig doctor and prescriptions written by the competent but still inexperienced practitioner, and I know what happened to the patients who took those different prescriptions. [Laughter.]

Senator COPELAND. I think that we ought to say, in defense of Dr. Emerson, that he really did not intend, I judge, to reflect on those ancient remedies which are still considered to be good. What he was talking about was temporary medical opinion and temporary drugs.

Dr. BEAL. My personal opinion is that he really did not intend to say what his expressions indicated.

Now, instead of leaving it to the general agreement of medical opinion, it would have to be determined by the Secretary of Agriculture, and I suggest that it would accomplish the same end and be much simpler if we should strike out all of that complicated language and insert the following:

"A drug shall be deemed to be misbranded when any part of the labeling is contrary to the opinion of the Secretary of Agriculture."

Another very important feature of section 8 is found in paragraph (b), which enumerates a list of drugs designated as "narcotic or hypnotic substances" and their derivatives "by actual or theoretical chemical reaction", the quantity or proportion of which must be declared on the label and accompanied by the statement, "Warning—may be habit forming."

Here we see illustrated the common mistake of the layman, namely, that the word "narcotic" is synonymous with the word "habit-forming", whereas as a matter of fact there are dozens, and perhaps hundreds of drugs, as for example, the oils of lemon and orange and other common and essential oils which have well defined narcotic properties, but are not in the slightest degree habit forming.

Another objectionable feature of this paragraph is the inclusion of "theoretical chemical derivatives." Anyone familiar with the hypotheses of chemical substitution is aware of the fact that almost any chemical compound can be conceived as theoretically a derivative of almost any other compound, even though they cannot be so derived in practice.

Another objection I have to this section is that it authorizes the Secretary to add to the list of habit-forming drugs such other substances as "as he may find to possess narcotic or hypnotic properties." There is a confusion of the words "narcotic" and "hypnotic" with "habit forming", and yet there is a very wide difference; we have dozens of drugs, we have hundreds of drugs, which are distinctly narcotic in their properties; but they are not in the slightest degree habit forming.

You know what the oil of peppermint is, and that is a narcotic, as the oil of lemon is, or the oil of the orange, all of the common essential oils, but not one of them has the slightest habit-forming characteristics. Therefore this should have been preceded by the language "habit forming", then narcotic drugs.

As to these particular drugs included in this list, with one or two exceptions they are fairly well selected, but they should never be found in medicinal preparations without their presence in quantity and proportion being stated on the label.

Now, this got in by accident, but it is there:

> The Secretary is hereby authorized, by regulations prescribed after notice and hearing, to designate as narcotics or hypnotics within the meaning of this paragraph such other substances as he may find to possess narcotic or hypnotic properties.

Of course, we know that Judge Campbell would exercise that language rationally or properly, and we hope that his successors may do so, but there is no absolute certainty, and it is specifying acts which shall constitute crime, or turning over to an administrative officer of the Government the specifying of such acts, which should not be done.

If Congress does not want us to sell a particular drug, let it say so. There are not so many which are habit forming, and they can be stated in less language than is required to confer absolute authority on the Secretary of Agriculture in this respect.

Senator COPELAND. Of course, Doctor, the purpose of a Senatorial hearing is to apply the acid test to the language in the form of a bill.

I do not know who wrote it. I did not write it.

Dr. BEAL. Some professor evidently did. [Laughter.]

Senator COPELAND. Do not misunderstand me. I am for the bill, but I do think we should add what you have suggested before "narcotic" or "hypnotic"—habit forming. That sounds sensible to me, but we must not be too harsh on those who actually produced the original act.

Dr. BEAL. If you knew how harsh they were on some of us. [Laughter.]

Senator COPELAND. We are here to try to modify the language and make it more scientifically accurate, if we can.

Dr. BEAL. They never put cushions in their gloves when we visited them.

Senator COPELAND. There has not been a lack of that as far as you are concerned, Doctor.

Dr. BEACH. I wish also to call attention to another serious defect in this last mentioned authority conferred on the Secretary of Agriculture.

We have, as the honorable chairman is well aware, a number of large manufacturing establishments in this country who are spending hundreds of thousands of dollars in the attempt to develop new drugs which assuage or control pain, or produce hypnotism or sleep, but possessing none of dangerous qualities that many of our known drugs possess.

Now, under this particular authorization of the Secretary, the work of many experts, research chemists, spending many hundreds of thousands of dollars, might be wiped out of existence.

We do believe, Mr. Chairman, and we believe it very thoroughly and sincerely, that the protection of the public health is paramount to every other interest, but we also want that interpreted in connection with this further statement, that where health can be equally well or better protected while at the same time taking care of the legitimate commercial or industrial matters, that that is preferable to one which is universally destructive and which does not at all take into consideration any of the byproducts of such legislation as we may adopt.

Senator COPELAND. You remember this morning that Mr. Campbell spoke about some scientific committees. I think that he has in mind—certainly I have—that there shall be written into this bill a provision for the raising of such committees, to have it specifically stated that this organization and that organization and the other organization shall be represented, because it stands to reason that the Secretary of Agriculture would be a qualified physician or a pharmacist only once in a thousand years.

He has to depend on somebody, and I know enough about the Department, and the food and drugs organization, to realize that they welcome the inclusion in the bill of an arrangement for a committee such as I have indicated.

Dr. BEAL. That is why we are here. We have been chasing them all over the city of Washington to find out what is in this bill.

Senator COPELAND. You have it here now, and let us fix it up and get it right.

Dr. BEAL. Unfortunately, I sat so far back in the room this morning that I could not hear Judge Campbell's very excellent and illuminating address.

Senator COPELAND. I assure you, Doctor, on that point, and Mr. Campbell will correct me if I am wrong, that he clearly intimated or directly stated, that it was his intention to have such a scientific committee. Am I right or wrong on that?

Mr. CAMPBELL. Yes. I said that in meeting the obligation of the Secretary in fulfilling the administrative provisions of this particular section 10 and other sections, where he was required to make findings of fact that have the force and effect of law, it was the purpose to make an appraisal of the scientific knowledge available on this subject, on the question of food standards, by the designation of committees qualified because of their eminence. In the consideration of drug questions, where there is a similar obligation imposed, or similar authority extended, they will function the same way.

Dr. BEAL. I think that would be a most excellent extension of the present activities of the Bureau. I do believe that if the Bureau would permit us, in pharmacy, to designate the men of standing, not only scientific standing, but of character and who would have an occasional friendly conversation with us, that we could discuss these propositions in a give-and-take manner, but nevertheless a friendly manner, and that we would not have these disputes.

I do not think that the best result is obtained in the enforcement of law by trying to slip around and catch somebody and to bring them before the courts or the public. That, of course, must be done if the man won't behave himself, but I think that an administrative officer best performs his function if he keeps in touch with the people to whom his law applies and helps them to understand it and to execute it.

When our dear old friend Harvey W. Wiley was living, we did not have any difficulty in getting next to him and having understandings with him as to what was proper and right in the drug business.

Senator COPELAND. I am sure that you do not have any difficulty with Mr. Campbell.

Dr. BEAL. I hope we do not, or shall not. [Laughter.]

The remaining language of the paragraph leaves something to be desired in the way of clarity.

Paragraph (e) provides that a drug if not recognized in the U.S.P. of N.F. shall be deemed to be misbranded if "its label fails to bear the common name of the drug, if any there be, and (2) the name and quantity or proportion of each medicinally or physiologically active ingredient thereof."

What common name is referred to? Sometimes a drug has one common name in Portland, Oreg., and a different one in Portland, Maine. Take our good old friend, known in Pennsylvania as "Black Snake Root." That has a different name in Ohio, still another one in West Virginia, and still others in other States, so what name should be used in that case, and I could go on and name any number of drugs which have different names in different localities, and certain names which apply to a dozen different drugs.

Take Snake Root. We have all kinds of Snake Root, all representing different species of drugs having different medicinal qualities. Then this refers to the name and quantity or proportion of each medicinally or physiologically active ingredient thereof, in plain English. This means complete formula disclosure, that is, that the complete disclosure of the ingredients and their proportions, shall be stated on the label, and that they shall be stated in the simplest common language, in English.

You know that there is a great deal of difference between the use of English and Latin in medicine. The difference between a prescription in Latin and a prescription in English is always $0.50. [Laughter.]

These arguments for and against formula disclosure are so old that they have become classics, and we know just what arguments will be offered in favor of it, and what arguments will be offered in opposition to the proposition to print the formula on the label.

One of the old arguments in favor is that the patient should know what he is taking. That may have some measure of value to him, but how much? He would not know anything more when he did have the names of those drugs.

A really worth while argument in favor if it is this: That a physician called upon to treat a patient should have the opportunity of knowing medicinal agents have been previously administered to that patient. That is a really worth while, valid argument, that a physician should have the opportunity of informing himself as to what his patient had been previously taking.

There are also some arguments against it, and one argument is this: That a great many people have the pernicious habit of constantly wanting to experiment, and you put the formula on the back of a preparation, and they would like to know what those different drugs are. How many druggists have had a patient come in and ask to see some yellow dock root or dandelion root or wild cherry bark or something else, and you ask them why they are interested, and they will tell you that they want to take it home and use it as a tea.

Another argument, from the standpoint of the proprietary manufacturer, is that the printing of the formula on the label will have the effect of piracy, permitting piracy. Some unscrupulous druggist will say, when the customer comes in and asks for a bottle of, say, Dr. Jones' Hair Preparation, "Why, Dr. Jones' Preparation costs you a dollar, and here is my own; look at it, and you will see that the formula is exactly the same, and you can have my bottle for 49 cents."

That is a valid objection from the proprietary man, a really valid objection, which we should take into consideration, although it should not be a controlling incident in this.

There are some considerations which have been very generally overlooked both by the friends and by the enemies of the formula disclosures, but that is the general effect that it would have upon the classification of proprietary remedies.

Proprietary remedies are now divided into two classes, those of secret composition and those of open composition, and if we are going to have them all open compositions, we shall have only one class. In the estimation of the consuming public, they will all be put in the same class; in other words, when people read those formulas, they will discover to their surprise that they are all in the United States Pharmacopœia and the United States Formulary, and that the written prescriptions which their physicians give them bear a very close resemblance to the formulas printed on the proprietary drugs.

I am a pharmacist, and I like to see a pharmacist get a fair deal. The physician can, in a measure, protect himself against it, but where does the pharmacist come in, who tries to make a living by compounding physicians' prescriptions?

If the public will be materially benefited, there is only one answer. If we are certain that the public will be materially benefited, the only answer is to put the formula on the package.

Senator COPELAND. Well, did you hear me ask a question of Mr. Campbell this morning?

You may remember that during my administration of the health department, we tried the sanitary code, and we had this argument, and I see many familiar faces here, and we finally reached the conclusion that if the formula were filed with the commissioner of health, we could then determine whether or not there were any incompatibles in it, or poisons, or improper drugs, and then by giving the serial number, we would be prepared to administer the law.

Mr. Campbell this morning took a strong ground against that, said that that was not sufficient, that it was right for the public to have this information because the man is self-prescribing, that he is his own doctor and he is entitled to know what he is taking.

I would like to have you state, out of your wide experience, how you think the public would be best protected. That is what we as a Senate committee are here for. Regardless of any profession that I may have, my duty here is to do what we can to protect the public, and I would like to have you present your views on it.

Dr. BEAL. My personal feeling, expressed in various papers written and various talks, is that the public will be best protected and the general good will be best benefited by disclosing the formula to some administrative board, with proper provision that that board shall not publish it generally, and permit them to pass upon it and say whether it is a safe remedy for the purpose for which it is intended.

In other words, to disclose it to the administrative body instead of giving it wide publication.

Some people say, "Why, that is a valuable preparation; why don't the man get a patent on it?" The patent law says that he shall have a patent for a new and useful invention. That law is like the Food and Drugs Act. It is not what we say the words mean, but it is the interpretation which the officer gives to it, and they have interpreted that to mean that a man can make something very useful and not get a patent on it.

To give an illustration, many of you have had the opportunity to taste fluid extract of bucui, and if you have tasted it once, you will never forget that flavor. It is the most difficult of all flavors to overcome or hide or disguise. If I knew how to disguise it so that it would not be so revolting, I could sell the secret tomorrow for $1,000.

But suppose that I went with that secret to the Patent Office and I said, "Here, I have something and I have invented it myself. It is an invention; it is a new thing. It is a useful thing."

They would say, "What is it?"

I would say, "It is making flavoring agents in fluid extract of bucui so as to conceal its nauseous flavor."

"No; you cannot have a patent on that. If you could prove that you had administered something to the fluid extract of bucui which had made an entirely different compound out of it, changed its nature, then we might give you a patent."

But if I did something to the fluid extract of bucui which changed the nature of it altogether, it would no longer produce the desirable effects of fluid extract of bucui on the human system.

So there is some excuse in certain cases for a certain degree of secrecy in medicine, but it in no case should be permitted to interfere with the general public interest.

Now, another statement in this paragraph contains the term "physiologically active ingredients."

Senator COPELAND. Where is that?

Dr. BEAL. On page 11.

Senator COPELAND. Yes; on line 4.

Dr. BEAL. Now, I assume that the professor who composed this bill, by the use of that language, meant to say something which had considerable physiological activity, that he meant that there should be placed on the package the names of those substances on which the proprietary relied to substantiate his claim for therapeutic value. That was the intention, but it does not state it.

Physiological activity will comprehend any degree of activity from the most minute degree to the most potent activity, so that that language should be modified or changed.

(After an informal discussion as to how much longer the doctor cared to speak:)

Senator COPELAND. The doctor has said that he can submit the rest of his address in writing, and let me say to the witness that, after all, this is a hearing and we are simply making a record, and this record will be used by every member of the Senate who desires to participate in the debate. There is no particular reason why all of the arguments should be made for the benefit of Senator Caraway and myself, and if the Doctor is willing to put the rest of his paper into the record, it would help us a lot, because there are many others here who

take the same position in opposition to the bill, and even more violent opposition, because I think that the attitude of our present witness is to be helpful and constructive, but there are some, I think that would like to tear the bill apart.

So I think that, without the slightest desire to cut you off, we will accept your proposal and put the remainder of your remarks in the record, but in the meantime you may take 5 or 6 minutes to close your argument.

Senator CARAWAY. Are his ideas—what he wants to say—included in his paper there?

Dr. BEAL. We have included our ideas in the form of amendments to the present act.

Senator CARAWAY. And they are included in your paper?

Dr. BEAL. They are submitted with the statement.

Senator COPELAND. Furthermore, Doctor, if upon further consideration there is any further material that you want to put into the record, you may do so.

Go ahead and finish, then.

Dr. BEAL. The only thing I will say in addition is this, that we are heartily in favor, 100 percent in favor of the proposition to control, and to effectively control, false or fraudulent advertising.

We are not entirely certain whether that function can be best discharged by the Federal Trade Commission or by the authority provided for here. That is a board which has done some very remarkable work under some very disturbing circumstances, but, in spite of a good deal of adverse criticism, I think that if that board were given sufficient authority and adequate support, it could accomplish almost an entire revolution on the subject of medical advertising, or, as they state, advertising medicinals. For my part, I would like to see this false advertising exterminated altogether. I lose my temper every evening when I try to get some music over the radio and my ears are assaulted with some outrageous mass of nonsense concerning some medicinal preparation.

There is one other thing I wish to call attention to, in respect to the list of diseases which might not be mentioned on the label, or concerning which you may not or shall not advertise a preparation in treatment of. That is not so bad, because most of the diseases named there are such as should not be self-treated by the patient.

I want to call your attention to the fact that there are not as many of those preparations as you have been led to believe, perhaps. Suppose that you go to your drug store and say, "I want you to give me a patent medicine for tuberculosis or consumption."

You would be told, "I have not anything of that kind."

I do not know any patent medicine of that kind. If you were to ask, "Give me one for Bright's disease," you would be told, "I do not know anything of that kind," and so as you go down the list, it is not there. There are not half-way as many as the public has been led to suppose that there are. Propaganda has been carried on to make the general public believe that the shelves of the average drug store are loaded down with alleged cures for these diseases for which there is no exact cure.

Then the provision goes on and gives the Secretary of Agriculture the power, whenever he deems it necessary, to add to the list of

diseases or ailments for which nobody may advertise a medicine. Think of that.

Now, psychologically speaking, this is one of the most adroit sections of the bill. If this section started out with the last provision put first, that the Secretary of Agriculture should have the right to prescribe by regulation what medicines might not be advertised, you would hoot at the proposition, so it is cleverly covered up by introducing this list of twenty-five afflictions, beginning with albumin uria and ending with whooping-cough, nearly all of which are such that they cannot be treated with self-medication; and this provides that he shall have the authority to put others on this list, and there is no limit. He can say that it is patently contrary to the public interest that a man should treat himself when he can be treated so much better by a physician. I agree. If I had my way about it, every case of illness would be diagnosed and prescribed for by a competent physician, who would write a prescription and take that prescription to a competent pharmacist and have it filled by a pharmacist, but that is impossible.

Suppose that you are living way out in the country, 42 miles from the nearest registered pharmacist and 18 miles from the nearest physician? If I had time I would tell you an interesting experience I had, but I want to pass on to the next.

This licensing of factories and laboratories may possess the same element of value, but also it presents a very great menace. Consider the thousands and thousands of factories, of manufacturies and laboratories which can be inspected with no control over the appointment of the inspector except the discretion of the Secretary of Agriculture. To police all of this would mean a party of political appointees approximating the United States Army in number, with real authority, with the authority of life and death over every establishment that they inspected, and sometime they might exercise that authority unwisely.

Just a few words with reference to penalties. I won't take up your time by reading them all, but I want to call your attention particularly, Mr. Chairman, to paragraph 5 in section 17 relating to penalties. That reads:

> The introduction into interstate commerce of any food, drug, or cosmetic, if the manufacturer, processor, or packer does not hold a valid permit when so required by regulations under section 12.

In other words, you are required to hold a permit by a regulation issued by the Secretary of Agriculture, and if you don't have a permit, then you have committed a crime; and if you commit this crime, it is evidently one that you must have committed voluntarily, and in that case you will be subject to the full penalty of the law, namely, $10,000 fine and a maximum of 3 years in the Federal penitentiary, and not for violating the law. Your product can rate 100 percent in purity or in the manner of branding or in the manner of advertising, but if you have dared to send that in interstate commerce without having a permit from the Secretary of Agriculture, you are just in bad. You have not violated a law, but you have violated a regulation.

I say that that is fundamentally the creation of a crime by action of the Secretary of Agriculture, because unless he passes such a regulation the crime does not exist. He creates it whenever he passes the regulation, and you violate the regulation and then you are due for a fine and a penitentiary sentence.

Just one other point and then I will spare you, and that is with relation to the general administrative provisions in Section 23. Now, with any statute of an administrative character, it is almost always provided that the administrative officer shall have authority to make such rules and regulations as may be necessary to carry the provisions of the law into effect. It is the court which determines what regulations are necessary, but here we see an evident intent to go to the extreme limit of whatever authority can be vested in the making of regulations in the Secretary of Agriculture.

Take the matter of provisions for hearings. A hearing is in the nature of a judicial proceeding. A hearing before the Secretary of Agriculture bears the same relation to the proceedings of a Federal District Court. That is roughly analogous to the proceedings in a magistrate's court, in its relation to the court of common pleas, or a grand jury.

Now, consider how these preliminary proceedings are to be carried out. We do not expect, of course, that in the hearings in magistrate's courts the procedure shall be with the same formality that is required in courts of record, but we do expect, and the law demands, that the procedure shall be such that the substantial rights of the act used are properly protected, that you can appear in person, or can have a legal representative.

But here we find a set of regulations which, if they are sustained by the courts, create an entirely different situation. For instance, by considering paragraph 5, Section 17, we discover it is an offense to violate a regulation, and, secondly, we discover that certain provisions set forth in such general terms that the specific acts necessary to constitute an offense must of necessity be prescribed and defined by regulation, in other words, that the real obligations for which penalties may be imposed shall be created by the administrative officer.

Then we find that in questions not susceptible of exact proof, by experimental evidence, as, for example, what shall be accepted as contrary to the general agreement of medical opinion, the opinion of the agent who conducts the hearing will control, since he will designate the particular authority which will be accepted.

We find in paragraph (a), section 23, that "The Secretary of Agriculture is authorized to prescribe such regulations as he may deem necessary for the efficient enforcement of the functions vested in him"—not such as are necessary to carry into effect the provisions of the law, but such as he may deem necessary to discharge effectively the functions vested in him as he interprets these functions.

We find, finally, that the Secretary's regulations are to be imbued with the force and effect of law as to the notice and conduct of hearings. Under this, the notice of hearing may be 30 days or 24 hours. The Secretary has power to decide whether the accused may be represented by legal counsel, or must present his own defense, and can decide the method of procedure, the kind of evidence to be admitted or rejected.

The Secretary is not required by the law to specify the authority upon which he relies to support his conclusions that an article is adulterated, misbranded, or contrary to the general agreement of medical opinion, further than the report of an analyst who may have made an assay, and he may reject the opinions of standard medical

authorities on therapeutics with the mere statement that that is only hearsay evidence.

Finally, we find that paragraph (c) provides that—"Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose."

He may designate the janitor, if he wishes. It is there in the law; nothing to limit it. Of course, Judge Campbell would never appoint anyone but a competent officer, but that provision is written authorizing the selection of any employee. Under this, the subordinate who writes the opinion, decides the procedure and the kind of evidence that is to be introduced, writes his own conclusions into the record, and turns the record over to the Secretary of Agriculture, and he accepts this as conclusive of the facts.

Senator COPELAND. Do you bear in mind that Mr. Campbell suggested an amendment at this point?

Dr. BEAL. Yes; and I think it was an excellent suggestion in the line of real justice and fairness, but, taking the terms of the bills as written, the accused is first required to plead his cause in a court, the presiding officer of which first makes the law, and in such case the law is his own regulation, and that presiding officer prescribes the method of procedure, and that presiding officer also prescribes the rules of evidence, and, in addition to these functions, he also operates as a prosecuting witness, judge, and jury, and then, if in this case he finds the accused guilty, the presiding judge next appears as a prosecuting witness in the court above, which is the Federal District Court.

Senator COPELAND. Thank you very much, Doctor. The remainder of your address may, as I stated previously, appear in the record.

Dr. BEAL. In addition to formula disclosure the Secretary is also authorized to require the appearance on the label of such further information as "he may deem necessary." This in effect confers upon the Secretary of Agriculture practically unlimited power over the labeling of medicinal products of every kind other than those recognized in the U.S.P. and N.F.

Paragraph (f) of this section requires that U.S.P. and N.F. drugs be packaged and labeled as directed in these volumes, as for example, the shape and color of mercury bichloride tablets, the size and color of bottles containing spirits of nitrous ether, etc.

Paragraph (g) authorizes the Secretary to decide as to what drugs are liable to deterioration, and to prescribe the style of packaging and labeling of such drugs. Under the language employed this will apply to those of the U.S.P. and N.F. and to all others which he may declare liable to deterioration.

The language of the first clause of paragraph (h) that a drug will be misbranded "(1) If its container is so made, formed, or filled as to mislead the purchaser" leaves much to be desired, since it does not specify the kind of acts from which an attempt to mislead the purchaser can be inferred. Such omissions must, of course, be supplied by regulations.

Paragraph (i) of this section would by legal enactment destroy the distinction between "antiseptics" and "disinfectants" as hitherto recognized by authors and teachers.

Since the time of Pasteur and Lister, antiseptics have been understood to be such agents as are unfavorable to or which retard the growth of micro-organisms, without necessarily destroying them, while the terms "disinfectants", "bactericides", and "germicides" have been understood to refer to agents which will absolutely destroy the lives of such organisms. Disinfectants may be reduced to antiseptics by mere dilution, but all antiseptics do not necessarily become disinfectants through concentration.

Under the operation of this paragraph nothing could be legally called an antiseptic unless it was capable also of acting as a disinfectant, germicide, or bactericide, and labeled with the kinds of organisms it is capable of destroying, and the length of time it must remain in contact to cause their death.

As the distinction between antiseptics and germicides is an invention of Mother Nature herself we venture the prediction that it will continue to exist even through the mighty voice of Congress shall decree that it may not be mentioned on the label.

Section 9. False advertisement.

By paragraph (a) of section 9—

> An advertisement of any food, drug, or cosmetic shall be deemed to be false if in any particular it is untrue, or by ambiguity or inference creates a misleading impression regarding such food, drug, or cosmetic.

Here again is exhibited the mistaken impression that the therapeutic action of a drug can be asserted with the same precision as the reactions upon each other as well-known chemical agents. Unfortunately this is not true, and under the language employed the opinion of the Secretary of Agriculture would supply the standard which must be met, and this in many cases could not be ascertained until after the goods had been distributed in interstate commerce.

Paragraph (b) recites that—

> An advertisement of a drug shall also be deemed to be false if it includes (1) the name of any disease for which the drug is not a specific cure but is a palliative, and fails to state with equal prominence and in immediate connection with such name that the drug is not a cure for such disease; or any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.

This language is nearly identical with that in section 8 dealing with the misbranding of drugs, and while to a layman it may seem to be definite, its real meaning when critically examined is seen to be very uncertain. It employs the same ambiguous and undefined terms "disease", "specific cure", and "palliative", and also refers to that very uncertain thing "general agreement of medical opinion." According to the meaning attached to these terms the same advertisement may be construed to be either true or false, as will best suit the opinion of the administrative officer. In other words, the standard of truth and falsity will be the opinion of the Secretary of Agriculture.

These provisions are unsound for the reason that the uncertainty of construction which they permit would preclude the manufacturer from knowing what his legal obligations were. He might advertise his product according to the opinions of the best medical authority available and still find himself criminally liable through a one-sided construction of the statute. He might consult all the authors in a medical library and in the end find his advertisement condemned

by a single individual in the Food and Drugs Administration who preferred to follow a different authority.

Paragraph (c) of section 9 enumerates an alphabetical list of 37 different kinds of ailments, beginning with "Albuminuria" and ending with "Whooping cough" for which the advertisement of any drug in treatment shall be deemed to be false.

In another subdivision of this paragraph the Secretary is given blanket authority to add to this list such additional ailments as he considers should not be the subject of self-medication, and for which no remedy may be advertised either directly or indirectly.

From the standpoint of applied psychology this is probably the most clever paragraph in the entire bill. If the paragraph simply authorized the Secretary to designate a list of affections for which remedies might not be advertised, there would be a general outcry against the proposition, but by cleverly prefacing it with a list of diseases not ordinarily amenable to self-treatment the attempted vast extension of the Secretary's authority is not so plainly evident.

The naming of this large number of diseases also suggests a desire to create a popular belief that package remedies the labels of which indicate that they are intended for the treatment of such ailments are fairly numerous, whereas, as a matter of fact, they are not to be found in the average drug store, and exist only in holes and corners, or are being put out by that class of legally registered physicians who carry on a sort of mail-order business.

A very remarkable provision in this paragraph is that "no advertisement shall be deemed to be false—if disseminated to members of the medical and pharmacological professions only or appears in scientific periodicals".

This leads to the queer situation that the same advertisement will be either true or false according to the medium in which it appears. If published in a medical journal, it will be legally true even if it be clearly and demonstrably false. If published in a daily or weekly newspaper, it will be criminally false even if it be literally and absolutely true. The man who prints a knowingly false advertisement in a medical journal is to go free; but the man who prints an entirely truthful advertisement in the daily press will be fined and sent to jail.

Taken as a whole the scope of the language employed in this section is such that the Secretary of Agriculture can by regulation prohibit the advertisement in daily and weekly newspapers of practically every remedy now offered in interstate commerce.

Section 10: Tolerance for poisonous ingredients in foods and cosmetics and certification of coal-tar colors.

Section 10 authorizes the Secretary to determine what added substances in food or cosmetics "is or may be injurious to health", and either to prohibit the use of such substances or to limit the amount which may be present. It also authorizes him to certify to the harmlessness of certain coal-tar colors.

Section 11: Definitions and standards for food.

This section in very broad terms authorizes the Secretary to "establish, promulgate, and enforce definitions of identity and standards of quality and fill of containers of any food." In other words, instead of dealing with such matters by express provisions of law they are to be left wholly to the discretion of the Secretary, who may change his standards whenever he deems it to be necessary.

Section 12: Licensing of factories and laboratories.

Section 12 authorizes the Secretary of Agriculture in broad and general terms "to make such regulations governing the conditions of manufacturing, processing or packing" of any class of food, drugs, or cosmetics, "as he may deem necessary," and to require all such manufacturers, processors, or packers "to hold a permit conditioned on compliance with such regulations."

The Secretary is authorized to issue permits for such periods of time as he may prescribe, and to suspend immediately the permit of any establishment where the regulations are violated.

Authorized agents of the Secretary shall have free access to establishments operating under permit, so see that the regulations are being complied with, and denial of such free access will be sufficient ground for the revocation of the permit.

Section 13: Factory inspection.

Section 13 expands the powers granted in section 12, by authorizing any designated agent of the Secretary, after first obtaining permission of the owner—

> (1) To enter any factory, warehouse, or establishment in which food, drugs or cosmetics are manufactured, processed, packed, or held for shipment in interstate commerce, or are held after such shipment, or to enter any vehicle being used to transport such food, drugs, or cosmetics, in interstate commerce; and (2) to inspect such factory, warehouse, establishment, or vehicle and all equipment, methods, processes, finished and unfinished materials, containers, and labels there used or stored.

The provision that the inspector must have permission from the owner or manager before entering upon his inspection means nothing, since those who do not permit free access of inspectors to their establishments may not ship their products in interstate commerce.

Thus by the terms of sections 12 and 13 the entire process of food, drug, and cosmetic manufacture, and of their labeling and shipment is placed within the unrestrained control of the Secretary of Agriculture. The denial of free access of inspectors, or the keeping secret of a single article of equipment, of a single item of any method or process of manufacture, or of any other item of information demanded will be sufficient ground for excluding the entire production of a factory or laboratory from interstate commerce.

No method for an appeal from or the review of the Secretary's decisions is provided, and no limitation is placed upon his power to issue, withhold or revoke permits, except that his will must be expressed in the form of regulations, which under other sections of the bill he has almost unlimited authority to issue. Proceedings against violators of regulations are to be through injunction and contempt of court, proceedings in which the accused cannot demand a trial by jury.

To provide for the inspection of the thousands of factories and laboratories devoted to the production of foods, drugs, and cosmetics we can envisage a body of inspectors approximating the United States Army in numbers—a body of political appointees having the power of life and death over the establishments inspected that would make the Secretary of Agriculture the most potent political factor in the Federal Government.

Sec. 14. Records of interstate shipment.

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By section 14, carriers and receivers of food in interstate commerce are required to submit records to authorized agents of the Secretary. Refusal to submit such records is made a criminal offense.

SEC. 15. Investigation and Institution of Proceedings.

Section 15 authorizes the Secretary of Agriculture to conduct investigations either through his own appointees or through officers of any State, Territory, or political subdivision thereof.

The Secretary, before reporting violations to the United States attorney for prosecution, is required to afford opportunity for hearing to interested parties "in accordance with such regulations as the Secretary shall prescribe." There is, however, no provision for such preliminary hearing when the violation is reported by an officer of a State, Territory, or political subdivision thereof, so that when a United States attorney institutes a suit on information filed by a State or territorial official the only notice the defendant may have is when he is called upon to answer criminal proceedings in a Federal District Court.

SEC. 16. Seizures.

Paragraph (a) of Section 16 authorizes seizure and condemnation of articles adulterated or misbranded under the Act, or which are the products of establishments the operators of which do not hold permits as required by the regulations.

Parties to a condemnation proceedings may, by obtaining an order from the court, secure a "representative sample of the article seized," for the purpose of a duplicate analysis, but under the bill as written the defendant apparently cannot demand such sample as a matter of right.

Methods of procedure are provided for the destruction, sale, or other disposition of articles condemned. Under certain conditions articles condemned for adulteration or misbranding may be returned to the owner under bond, but when condemned because the owner did not possess a permit as required by regulations the articles must be destroyed, and the cost of all proceedings will be assessed against the owner.

Agents of the Secretary of Agriculture are relieved of personal responsibility for wrongful seizures when they have acted by his discretion or by direction of duly designated officer of the Food and Drug Administration. In other words, the Secretary can authorize his agents to perform unlawful acts without danger to themselves.

SEC. 17. Penalties.

The following acts are specifically prohibited—

1. The introduction into interstate commerce of any adulterated or misbranded food, drug, or cosmetic.

2. The receipt in interstate commerce of any such adulterated or misbranded article, or the delivery or proferred delivery of the same.

3. The dissemination of any false advertisement by radio-broadcast, United States mails, or "interstate commerce."

4. The "dissemination of a false advertisement by any means."

5. "The introduction into interstate commerce of any food, drug, or comestic if the manufacturer, processor, or packer does not hold a valid permit when so required by regulations under section 12."

Note that the crime in this case is not the shipment of an adulterated, misbranded, or falsely advertised article, but its shipment without a permit from the Secretary of Agriculture. If the article

rates 100 percent in quality and in the truthfulness of its labeling and advertising, its shipment without the prescribed permit will nevertheless be a criminal act for which the full penalty of the law may be invoked.

6. "The refusal to permit access to or the copying of any record as required by section 14."

Violation of any of the foregoing prohibitions is declared to be a misdemeanor. A first offense is to be punished by imprisonment for not more than 1 year or a fine of not less than $100, nor more than $1,000, or both fine and imprisonment. For subsequent offenses imprisonment may be 2 years and the fine $3,000, or both fine and imprisonment.

If the first offense is willful, the penalty is imprisonment for not less than 6 months, nor more than 3 years, and a fine of not less than $1,000, nor more than $10,000, or both fine and imprisonment.

Publishers are relieved of responsibility for false advertisements when they furnish the name and address of the person who authorized such advertisement. A dealer is relieved of responsibility when he can establish a guaranty signed by a person residing in the United States, to the effect that the guarantor accepts full responsibility for any violation of the act.

The forging, counterfeiting, or simulation of any tag or label authorized by the Secretary of Agriculture may be punished by imprisonment for 1 year or a fine of $5,000, or both fine and imprisonment.

Section 18: Liability of corporate officers.

This section presents an expansion and amplification of the obligations of corporate officers as set forth in section 12 of the present Food and Drugs Act.

An employer is made responsible for the "act, omission, or failure of any officer, employee or agent" when the latter is acting "within the scope of his employment or office."

The violation of any provision of the act "by a corporation or association shall be deemed to be a violation of the individual directors, officers or agents * * * who authorized, ordered, or did any of the acts constituting in whole or in part, such violation."

Section 19: Injunction proceedings.

By section 19 the repetitious introduction into interstate commerce of any adulterated or misbranded food, drug, or cosmetic, or the repetitious dissemination of any false advertisement is declared to be a public nuisance, and United States district courts are authorized to restrain the same by injunction. Violations of such injunctions are to be summarily tried and punished as contempt of court.

In such injunction proceedings it shall not be necessary to show an intent to continue the offense.

Section 20: Imports.

Section 20 relates to the duty of the Secretary of the Treasury in respect to the importation of adulterated, misbranded, or falsely advertised food, drugs, and cosmetics; the delivery of samples to the Secretary of Agriculture, and the disposition of goods when condemned. In general these provisions correspond to requirements of the present Food and Drugs Act.

Section 21: Publicity.

This section requires the Secretary to periodically issue reports "summarizing all judgments, decrees, and orders which have been rendered, and all proceedings instituted and seizures made, including the nature of the charge and the disposition thereof."

Under this language a manufacturer's reputation may be permanently clouded by the charges made against him, even though the court may find him guiltless of the offenses charged.

This section also requires the Secretary to "cause to be disseminated such information regarding any food, drug, or cosmetic as he deems necessary in the interest of public health and for the protection of the consumer against fraud."

SECION 22: Voluntary inspection service.

Section 22 authorizes the Secretary to appoint what are termed "supervisory inspectors" to supervise and inspect all premises, equipment, methods, materials, containers, labels, etc., of manufacturers who file a request for such inspection.

If and as long as the reports of such supervisory inspectors are favorable such manufacturers of food, drugs, or cosmetics are to be permitted to mark their products in such manner as may be provided by regulation to show that they have been officially inspected and consequently that they have Government approval.

It would no doubt be very advantageous to a new firm struggling to get a foothold in the market to be able to have its products officially approved, signifying that they are as good as can be made, but this would not afford much satisfaction to firms which have been striving for half a century or longer to build up a reputation under their own brand and label.

The salaries of such supervising inspectors and other expenses incidental to the establishment and continuance of such service are, of course, to be paid by the firms receiving the service.

While called "voluntary inspection service", it is evident that if one establishment should adopt it, all others would be compelled to do likewise or have their products rest under suspicion that they will not bear official inspection.

SEC. 23. *General administrative provisions.*—In statutes of an administrative character it is usually provided that the administrative body shall have power to make such rules and regulations as may be necessary to carry the provisions of the law into effect. Such provisions have been frequently reviewed by the courts, and decisions are unanimous to the effect that they do not authorize administrative officers to extend the scope of the law by the imposition of obligations not expressed in the law itself, nor to read into the law meanings other than those plainly intended by the lawmaking body.

In the bill before us there is an evident intention to go to the extreme limit in conferring authority upon the administrative officer to influence the course of justice by reading into the law his own opinions expressed in the form of regulations, and, in many cases, to make his personal discretion the measure of the obligations imposed. Consider, for example, the provisions relating to the subject of hearings.

Preliminary hearings before an administrative officer are in the nature of minor judicial proceedings. As provided for in the existing Food and Drugs Act they bear a relation to United States district courts roughly analogous to the relation of ordinary magistrates' courts to courts of common pleas. While such tribunals need not

proceed with the stiff formality of courts of record, it is nevertheless presumed that they will have due regard to the substantial rights of the accused, that they will afford him opportunity for a fair presentation of his defense according to established rules of evidence before an impartial court, and that the questions presented will be decided upon their merits by a judge whose personal or official interests shall not be involved in the disposition of the case.

By comparing various provisions of S. 1944 relating to regulations and hearings the following conditions appear:

(1) That paragraph (5), section 17, makes it an offense, subject to the full penalty of the law, to violate a regulation prescribed by the Secretary, which regulation he may impose, amend, or withdraw at his own discretion.

(2) That certain provisions of the bill are set forth in such general terms that the specific acts constituting an offense must of necessity be prescribed and defined by regulation. In other words, that obligations upon manufacturers and shippers of medicinals will be such as the Secretary of his own motion may impose, and which may be one thing today and another and quite different thing tomorrow.

(3) That in questions of opinion not susceptible of exact proof or disproof by experimental evidence, as for example, what shall be accepted as "contrary to the general agreement of medical opinion", the opinion of the agent who conducts the hearing will control, since he will designate the particular authority to be accepted as representing the general agreement of medical opinion.

(4) That by paragraph (a) of section 23, the Secretary of Agriculture is authorized to prescribe "such regulations as he may deem necessary for the efficient enforcement of the functions vested in him"—not such as are necessary to enforce the provisions of the law, but such as he may deem necessary for the discharge of his functions as he may interpret them.

(5) That the Secretary's regulations are to be imbued "with the force and effect of law as to notice and conduct of hearings."

Under this the notice of a hearing may be 30 days or 24 hours; the Secretary can decide whether the accused may be represented by legal counsel or must present his own defense; can decide the method of procedure, the kind of evidence to be admitted, and the kind to be rejected. The Secretary is not required to specify the authority upon which he relies to support his conclusions that an article is adulterated, misbranded or contrary to the general agreement of medical opinion, and may reject the opinions of authors with whom he does not agree on the ground that printed books are only heresay evidence.

(6) That the purpose is to confer upon the Secretary power to control the result of such hearings further appears in paragraph (c) which provides that "hearings authorized or required by this act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose. The findings of fact by the Secretary shall be conclusive if in accordance with law."

Under this the subordinate who actually presides at the hearing will accept or reject evidence as it meets with his approval, write his own conclusions into the record, and these will constitute "the findings of fact" which the Secretary will accept as conclusive against the accused.

Thus from the terms of the bill as written the accused must plead his cause before a court the presiding officer of which makes the law—in such cases called "regulations"—who prescribes the method of procedure and rules of evidence, and in addition to these functions also officiates as prosecuting witness, judge, and jury.

And finally, having decided adversely to the accused, the judge in this preliminary trial next appears as prosecutor in the case before the Federal District Court.

Section 24: Liability for personal injuries.

Section 24 introduces something not common in statutory law, by providing that "a right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this act."

By a unanimous line of English and American decisions persons injured by a fraudulent or improperly labeled medicine can recover full damages in any court of competent authority, and in numerous instances such damages have been awarded. Why, therefore, encumber a United States statute with such a provision when an injured party already possesses an adequate remedy which can be pursued in the State courts?

The new provision if enacted would only be an invitation to blackmailing claims and suits.

At common law the defendent in a damage suit would have the right to plead contributory negligence and to show that the injury complained of was due primarily to the negligence of the plaintiff. That he would have such right of defense under this bill, if enacted, is not entirely certain.

Section 25: Separability clause.

This section provides that if any part of the act shall be declared unconstitutional, the remainder of the act shall not be rendered invalid thereby.

Section 26: Effective date and repeals.

Section 26 declares that the new act shall become effective six months after the date of its approval, at which time the present Food and Drugs Act shall cease to be effective, and also enumerated a list of other existing acts the provisions of which shall not be affected by the enactment of S. 1944.

A committee appointed by the National Drug Trade Conference has prepared a bill amending the Food and Drugs Act of June 30, 1906, as amended. I shall submit that bill for inclusion in the record at this point. In the suggested bill each section is designated by the number as given in the United States Code; also by section number of the original act; matter to be deleted is given in brackets; new matter in italic.

The bill reads:

A BILL To amend the Food and Drugs Act, June 30, 1906, as amended August 23, 1912, March 3, 1913, March 4, 1913, July 24, 1919, January 18, 1927, and July 8, 1930, for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, *cosmetics*, and liquors, and for regulating traffic therein, and for other purposes

8717. SECTION 1. *Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled*, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food, drug, *or cosmetic* which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed $500, or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than $1,000 or sentenced to one year's imprisonment or both such fine and imprisonment, in the discretion of the court.

8718. SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food, drug, *or cosmetic* which is adulterated or misbranded, within the meaning of this Act, is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in the original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such articles so adulterated or misbranded within the meaning of this act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods [or] drugs *or cosmetics*, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding $200 for the first offense, and upon conviction for each subsequent offense not exceeding $300 or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

8719. SEC. 3. That [the Secretary of the Treasury,] the Secretary of Agriculture [, and the Secretary of Commerce and Labor] shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods, [and] drugs *and cosmetics* manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such products are offered for interstate commerce, or for export or import between the United States and any foreign port or country.

8720. SEC. 4. That the examinations of specimens of foods, [and] drugs *and cosmetics* shall be made in [the Bureau of Chemistry of the Department of Agriculture] *such existing bureau or bureaus in the Department of Agriculture as may be directed by the Secretary of Agriculture*, or under the direction and supervision of such bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the [party from whom such sample was obtained] *manufacturer of such article if known or if unknown to the party who caused said article to be introduced into interstate commerce.* Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such [party] *manufacturer or such person who introduced the article in interstate commerce*, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

8721. SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of

the United States, without delay, for the enforcement of the penalties as in such case herein provided.

8722. [SEC. 6. That the term "drug", as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food", as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.]

SEC. 6. The term "food" includes all substances and preparations used for, or entering into the composition of food, drink, confectionery, or condiment for man or other animals. The term "drug" includes (1) all substances and preparations recognized in the United States Pharmacopœia or National Formulary or supplements thereto; and (2) all substances, preparations, and devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations, other than food, and all devices, intended to affect the structure or any function of the body of man or other animals. The term "cosmetic" includes all substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of, the person.

8723. SEC. 7. That for the purposes of this Act an article shall be deemed to be adulterated:

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary, *or supplements thereto*, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary, *and provided further, that no drug defined in the United States Pharmacopœia or National Formulary or supplements thereto, shall be deemed to be adulterated under this provision if it complies with the standard of strength, quality, and purity as determined by the test laid down in the United States Pharmacopœia or National Formulary or supplements thereto, notwithstanding that it may have been made by a modification of the official formula or directions made necessary to meet manufacturing requirements.*

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

In the case of confectionery:

If it contain terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by macreation in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consist in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

In the case of cosmetics:

If it contains poisonous or deleterious ingredients in such quantities as likely to be imminently dangerous to the user under the conditions of use prescribed in the labeling thereof, or when used under such conditions of use as are customary or usual.

8724. Sec. 8. That the term "misbranded", as used herein, shall apply to all drugs, *or cosmetics*, or articles of food, or articles which enter into the composition of food, the package, [or] label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food, [or] drug *or cosmetic* [product] which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

The term "package" or "original unbroken package" as used herein means the immediate container of the article which is intended to be delivered for consumption by the public. The term "label" includes all written, printed, and graphic matter in any form whatsoever accompanying any food, drug, or cosmetic.

That for the purposes of this Act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any [alcohol] morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis, chloral hydrate, [or] acetanilid, *or barbituric acid*, or any derivative or preparation of any such substances contained therein.

Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

Fourth. If it fail to bear the true name and address of the manufacturer, packer, seller, or distributor thereof.

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled [or], branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis, chloral hydrate, *or barbituric acid* or any derivative or preparation of any such substances contained therein.

Third. If in package form, the quantity of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count: *Provided, however*, That reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with the provisions of section three of this Act.

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or substances contained therein, which statement, design, or device shall be false or misleading in any particular: Provided, That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound," "imitation", or "blend", as the case may be, is plainly stated on the package in which it is offered for sale: *Provided*, That the term "blend" as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: And provided further, That nothing in this act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except insofar as the provisions of this act may require to secure freedom from adulteration or misbranding.

Fifth. If it be canned food and falls below the standard of quality, condition, and/or fill of container, promulgated by the Secretary of Agriculture for such

canned food and its package or label does not bear a plain and conspicuous statement prescribed by the Secretary of Agriculture indicating that such canned food falls below such standard. For the purposes of this paragraph the words "canned food" mean all food which is in hermetically sealed containers and is sterilized by heat, except meat and meat food products, which are subject to the provisions of the meat inspection act of March 4, 1907, as amended, and except canned milk; the word "class" means and is limited to a generic product for which a standard is to be established and does not mean a grade, variety, or species of a generic product. The Secretary of Agriculture is authorized to determine, establish, and promulgate from time to time, a reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer; and he is authorized to alter or modify such standard from time to time as, in his judgment, honesty, and fair dealing in the interest of the consumer may require. The Secretary of Agriculture is further authorized to prescribe and promulgate from time to time the form of statement which must appear in a plain and conspicuous manner on each package or label of canned food which falls below the standard promulgated by him, and which will indicate that such canned food falls below such standard, and he is authorized to alter or modify such form of statement from time to time, as in his judgment may be necessary. In promulgating such standards and forms of statements and any alteration or modification thereof, the Secretary of Agriculture shall specify the date or dates when such standards shall become effective, or after which such statements shall be used, and shall give public notice not less than ninety days in advance of the date or dates on which such standards shall become effective or such statements shall be used. Nothing in this paragraph shall be construed to authorize the manufacture, sale, shipment, or transportation of adulterated or misbranded foods.

8725. SEC. 9. That no dealer shall be prosecuted under the provisions of this act when he can establish a guarantee signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, *or who caused said articles to be introduced in interstate commerce*, to the effect that the same is not adulterated or misbranded within the meaning of this act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amendable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act.

8726. SEC. 10. That any article of food, drug, *cosmetic*, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except, that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 10a. Notwithstanding the provisions of section 4 the Secretary of Agriculture shall, before certifying any violation of paragraph third, "In the case of drugs", in section 8 of this Act, to any United States district attorney, to cause criminal proceedings to be commenced and prosecuted or to cause any seizure for confiscation by process of libel for condemnation, cause notice to be given to the person primarily

responsible for the representations alleged to be in violation of said paragraph third, and a day to be fixed upon which said person may be heard. No criminal proceedings shall be commenced nor shall any article of drug be proceeded against or seized for condemnation on the grounds that the label or package of said article of drug bears or contains any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein which is false and fraudulent, unless and until the Secretary of Agriculture shall have given the notice and afforded the opportunity for hearing as provided in this section.

At such hearing the party of parties interested may furnish evidence, either by himself or his representative, to justify the representations of therapeutic or curative value made in or upon such label, or package.

In the event such person shall refuse or is unable to justify such representations to the satisfaction of the person designated by the Secretary of Agriculture to hold such hearing, the secretary shall fix a reasonable time for such party to discontinue such representations or to make changes in or upon the label or package in the manner indicated by the Secretary. After such hearing the Secretary shall furnish such person a statement of his ruling and set forth his reasons therefor.

If such person at such hearing shall by proper evidence justify such representations or shall make changes indicated by the Secretary, the Secretary shall then furnish such person with a certificate that his rulings have been complied with.

In the event of the refusal or failure of such person to conform to directions of the Secretary or his designate within the time so fixed to discontinue representations or make changes in the package or label, the Secretary shall at once certify the facts as provided in section 4 of this Act.

Not more than one action based upon alleged false and fraudulent representations of therapeutic value shall be pending in the courts of the United States at one time until after there has been an adjudication that said article is misbranded within the meaning of said paragraph "third" herein mentioned.

After notice and upon good cause being shown by the district attorney that an emergency exists, the judge of the court in which said action has been commenced may enjoin the repetitious introduction in interstate commerce of articles similar to the article seized, until such time as the pending cause may be tried.

In the event, after the trial of said single action, there shall have been a final decree or judgment entered in favor of the Government, then further proceedings in libel for confiscation may be commenced against the article of drugs complained of and the label or package bear or contain similar statements, designs or devices and which have been shipped in interstate commerce.

The district attorney may apply to the district court in any jurisdiction where an article or drugs may be found, the label and package of which bears or contains any statement, design or device, concerning the therapeutic value of such article or of the ingredients contained therein which is false and fraudulent, upon a showing that an emergency exists and drastic action in the interests of public health is necessary, and obtain an order directing the United States marshal to impound such article pending further order of the court.

Appeals and other proceedings under this section may be had in accordance with title 12c, section 1121 (Judiciary Code No. 129).

10b. The term advertisement as used herein includes all representations of fact disseminated by the manufacturer, producer, owner, or distributor of an article of food, drug, or cosmetic, or by his authorized agent or representative in any manner by other than label, and excludes statements which involve matters of opinion where there is no exact standard of absolute truth. Any advertisement of food, drug, or cosmetic will be deemed false if in any particular representations of fact are untrue. The Secretary shall before reporting any violation of this act by reason of any advertisement of foods, drugs, or cosmetics for institution of criminal proceedings, afford due notice and opportunity for a hearing to interested parties.

The examination of advertising shall be made in a bureau of the Department of Agriculture as may be directed by the Secretary of Agriculture, and if it appears that such advertisement is false within the meaning of this section the Secretary of Agriculture shall cause notice to be given to the person primarily responsible for the representations appearing in such advertisement alleged to be in violation of this section, and the day fixed upon which said person may be heard. No criminal proceedings shall be commenced on the grounds that said advertisement is false, as defined in this section, until the notice and hearing provided for have been given and afforded. If it appears to the Secretary after such hearing that such advertisement is false as provided herein, then the Secretary shall direct that such party shall cease and desist from making the representations complained of, and in making such order the Secretary shall furnish to such person a statement of his ruling and set forth his

reasons thereof. In the event such person shall fail to cease and desist from continuing the representations in such advertising complained of, the Secretary shall at once certify the facts as provided in section 4 of this act.

10c. The dissemination of any false advertisement as defined in the next preceding section by any means for the purpose of inducing directly or indirectly the sale of foods, drugs, or cosmetics in interstate commerce is prohibited, and any person who violates or causes to be violated any of the provisions of paragraph A of this section, and who shall fail or refuse to comply with the cease and desist order as provided for herein, shall be guilty of a misdemeanor and shall, on conviction thereof be subject to a fine of not less than $100 nor more than $1,000, or imprisonment for not more than 1 year, or both such fine and imprisonment, in the discretion of the court.

8727. SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods [and], drugs, *and cosmetics* which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food [or], drug *or cosmetic* offered to be imported into the United States is adulterated or misbranded within the meaning of this act, or is otherwise dangerous to the health of the people of the United States, or if of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country in which it is made or from which it is exported or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within 3 months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

8727. SEC. 12. That the term "Territory" as used in this act shall include the insular possessions of the United States. The word "person" as used in this act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies, and associations. When construing and enforcing the provisions of this act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

Senator COPELAND. The statements of James W. Baldwin of the National Association of Broadcasters, and of Dr. D. Aitchison, president of the National Liberties Association, are presented for the record.

STATEMENT OF JAMES W. BALDWIN, ON BEHALF OF THE NATIONAL ASSOCIATION OF BROADCASTERS

Mr. BALDWIN. My name is James W. Baldwin, of Washington, D.C. I appear on behalf of the National Association of Broadcasters, the only trade organization representing the radio broadcasting industry of the United States. The National Association of Broadcasters has at present 283 members, and its membership does approximately 83 percent of the commercial broadcasting business of the country. Full details regarding this association are on file with the National Recovery Administration, which certified on November 14, 1933,

that this association "impose no inequitable restrictions on admissions to membership therein and is truly representative of the Radio Broadcasting Industry." For the record, I desire to file a list of the members of the National Association of Broadcasters, and also of its officers and directors, to form a part of this statement.

My appearance here is pursuant to a resolution unanimously adopted at the last annual meeting of the National Association of Broadcasters on October 11, 1933. This resolution reads as follows:

Resolved, That while the National Association of Broadcasters is eager to cooperate in protecting the public against exploitation through untrue or unscrupulous advertising, it believes that any legislation for this purpose must be reasonable and precise in definition, uniform in administration, and fair in application, and therefore this association must record itself as definitely opposed to the enactment, unless on the basis of many and far-reaching changes therein, of the bills to rewrite the Pure Food and Drug Law now pending in both Houses of the Federal Congress.

Radio broadcasting in America has grown in about 10 years to a point where today it is serving, day and night, something like 18 million radio-equipped homes. This growth and this service have been made possible solely by the revenue derived from advertising, which is the only source of income for our broadcasting stations. Like the other agencies of public information and entertainment made possible by advertising, including the newspapers and magazines, broadcasting has suffered heavily from loss of revenue as the result of general business conditions, and its concern now is not so much for possible profits as for its very life. The belief that this proposed legislation, if enacted in its present form, would result in a reduction of appropriations for wholly legitimate radio advertising by many millions of dollars, and thereby seriously endanger the stability of our entire industry, is our reason for appearing here before you.

This association has at all times stood squarely and unequivocally for the full protection of the public against exploitation by untrue or misleading advertising. In this connection, permit me to read into the record the code of ethics of this association, adopted March 25, 1929, and accepted and subscribed to by every member of the association. The code is as follows:

CODE OF ETHICS

1. Recognizing that the radio audience includes persons of all ages and all types of political, social, and religious relief, every broadcaster will endeavor to prevent the broadcasting of any matter which would commonly be regarded as offensive.
2. When the facilities of a broadcaster are used by others than the owner, the broadcaster shall ascertain the financial responsibility and character of such client, that no dishonest, fraudulent, or dangerous person, firm, or organization may gain access to the radio audience.
3. Matter which is barred from the mails as fraudulent, deceptive, or obscene shall not be broadcast.
4. Every broadcaster shall exercise great caution in accepting any advertising matter regarding products or services which may be injurious to health.
5. No broadcaster shall permit the broadcasting of advertising statements or claims which he knows or believes to be false, deceptive, or grossly exaggerated.
6. Every broadcaster shall strictly follow the provisions of the Radio Act of 1927 regarding the clear identification of sponsored or paid-for material.
7. Care shall be taken to prevent the broadcasting of statements derogatory to other stations, to individuals, or to competing products or services, except where the law specifically provides that the station has no right of censorship.

8. Where charges of violation of any article of the Code of Ethics of the National Association of Broadcasters are filed in writing with the managing director, the board of directors shall investigate such charges and notify the station of its findings.

In view of the large number of witnesses appearing before your committee, and in order to save time, we have prepared a statement covering certain of our specific objections to the proposed legislation. If it is the desire of your Committee, I will now submit this statement in writing, to be included in the full report of these hearings. If, on the other hand, you prefer to have me read it into the record, I shall, of course, be glad to do so.

It should be understood, in any event, that this statement does not purport to cover every feature of the proposed legislation to which objection might be raised by the broadcasters. Other witnesses, representing interests even more vitally concerned than we are with many of the specific features of the bill, are presenting in detail their reasons for opposing these features. Our statement is, rather, a broad indication of the reasons which compelled the broadcasters, by resolution unanimously adopted, to oppose the passage of the pending legislation in its present form.

The statement is as follows:

SPECIFIC OBJECTIONS OF THE RADIO BROADCASTING INDUSTRY TO S. 1944

1. The definition of "advertisement" on page 3, lines 15–17, is so broad as to include "all representations of fact or opinion disseminated in any manner or by any means."

Such a definition of advertising appears absolutely unworkable. An expression of "fact or opinion disseminated in any manner" covers practically every spoken, written or printed word. With such a definition, the prohibitions contained in section 17, subsections (3) and (4) (p. 23, lines 15–21) would apply even to the simplest oral statement.

Such a definition of advertising, if established by congressional enactment, would go far beyond the scope of the pending legislation. It would, in effect, place formidable barriers around the right of free speech. Within the field specifically covered by these bills, it would render any statement dangerous, unless such statement were based on an intimate and complete knowledge of scientific data.

Under so extraordinary broad a definition of advertising, and with the prohibitory provisions of this bill, there is hardly an advertisement of any food product, drug, or cosmetic appearing in our newspapers magazines, or broadcast from our radio stations, which is not at least open to attack. If such a definition is permitted to stand, there is scarcely a legitimate advertiser in this entire field who can feel himself reasonably secure from legal action, particularly since such action may and doubtless will be instigated in large measure by his competitors.

2. Section 9 (from p. 12, line 20, through p. 14, line 18) declares, in substance, that any advertisement of a food, drug, or cosmetic shall be deemed to be false if in any particular it is untrue, or by ambiguity or inference creates a misleading impression.

The broadcasters have no desire to enter into the argument concerning self-medication, with which this section is extensively concerned. They do, however, desire to point out three things:

(a) The phrase "if in any particular it is untrue" involves the setting up of an absolute standard of truth which, in the ordinary affairs of human life, is utterly unattainable. One may, in this connection, aptly quote Pilate's "What is Truth?" There is no piece of advertising copy in existence, no newspaper report, no public document, which could wholly meet such a requirement as this. Of course it will be urged that this phrase is not to be taken too literally, but a law that cannot be taken literally is a dangerous and bad law.

(b) The phrase "by ambiguity or inference creates a misleading impression" is just as dangerous as the phrase commented on in the preceding paragraph. How is the "impression" created by any given piece of advertising copy to be determined? What is meant by "misleading"? Even the most accurate and careful statement of facts, whether contained in an advertisement or in any other form of communication to the public, is subject to misinterpretation. A court has trouble enough in determining the correctness of a statement of facts; no one can even guess what would happen if it were called upon to determine legally the "impressions" created by "inference." Such a provision is a direct blow at all legitimate advertising. It would, if applied literally, threaten virtually every piece of advertising copy in the food, drug, and cosmetic field. If not applied literally, it would create a complete chaos of uncertainty.

(c) The provision that an advertisement of a drug shall be deemed to be false "if it includes the name of any disease for which the drug is not a specific cure but is a palliative" involves what appears to the layman to be a perfectly hopeless confusion of opinion. The "cure" of today is the "palliative" of tomorrow. Most people believe, for example, that aspirin "cures" headaches because it frequently stops them, but the headache itself may be merely the symptom of an ailment which the drug cannot affect. The use of such words as "cure" and "palliative" in legislation is certain to create endless confusion, because the words themselves are of such variable meaning.

3. Section 15 (from p. 19, line 11, through p. 20, line 11) directs each United States attorney "to cause appropriate proceedings to be instituted in the proper courts of the United States." This throws the initial determination of what constitutes unlawful advertising into a multiplicity of courts of presumably equal authority, resulting inevitably in hopeless confusion. An advertisement might and doubtless would be held truthful, and hence legal, in one court, and untruthful, and hence illegal, in another of like authority. It seems utterly impossible to avoid disastrous confusion unless the determination of what is and what is not permissible under the law is handled by a single judicial tribunal. This applies particularly to advertising which is interstate in character, and therefore is of special significance to the broadcaster.

4. Section 9 (p. 26, lines 11–25) gives to the district courts of the United States power to restrain by injunction the "repetitious dissemination by radio broadcasting—of false advertising." Here again, as in section 15, confusion is inevitable as a result of action by a multiplicity of courts. An advertisement may be found to be illegal in one court, legal in another, and summarily shut off by injunction in a third where the case has never actually been heard at all. Even the successful defense in court of an advertising statement will not afford full protection, because some other court may rule differently, thereby furnishing the basis for injunctions throughout the country. Unless there is set up a single tribunal with full authority for the entire Nation, subject only to the usual rights of appeal, this provision regarding injunctions is bound to give rise to vast confusion and manifold injustices.

Conclusion: It will be noted that the foregoing four specific criticisms of the bill fall into two groups. One—points 1 and 2—concerns what seems to be the impossibility of defining accurately enough for legal purposes what is meant by "truth" in advertising. It may be said that the broadcasters regard this defect in the proposed bill as fundamental, and that they can see no practicable way of extending the scope of such a bill beyond the deliberate misstatement of specific facts. Manifestly, an advertisement should not be permitted to state that the ingredients of a certain drug are so-and-so, when the manufacturer knows that in fact they are something else. When, however, legislation seeks to control the expression of opinion, or to set up a standard of absolute truth that is quite beyond the reach of the human mind, it is making the violation of its provisions inevitable and universal. A strict interpretation of the bill as it stands would destroy the entire advertising business of the United States; a liberal, i.e. lax, interpretation would lead to hopeless confusion.

The second group of criticisms (points 3 and 4) concerns the proposed administration of the bill. The primary object of any such legislation should be the protection of the public by making clear to advertisers what they may and may not legally do. The method of administration here set up appears completely to defeat this purpose.

Although reference has here been made to specific sections of the proposed bill, the objections raised to these sections apply likewise, though less directly, to other features of it, and therefore it is on the broad, general groups herein outlined that the broadcasting industry has recorded itself as protesting against the enactment of the legislation "unless on the basis of many and far-reaching changes therein."

LIST OF ACTIVE MEMBERS OF THE NATIONAL ASSOCIATION OF BROADCASTERS (AS OF NOV. 16, 1933)

Station WAAB, 500 watts, regional; Roy L. Harlow, assistant to president, Bay State Broadcasting Corporation, Boston, Mass.

Station WAAF, 500 watts, regional; W. E. Hutchinson, general manager, Drovers Journal Publishing Co., Chicago, Ill.

Station WAAT, 300 watts, regional; Paul H. La Stayo, general manager, Bremer Broadcasting Corporation, Jersey City, N.J.

Station WAAW, 500 watts, clear; F. P. Manchester, secretary, Omaha Grain Exchange, Omaha, Nebr.

Station WABC, 50 kilowatts, clear; Atlantic Broadcasting Corporation, 485 Madison Avenue, New York, N.Y.

Station WABI, 100 watts, local; F. B. Simpson, manager, first Universalist Society of Bangor, Bangor, Maine.

Station WADC, 1 kilowatt, regional; Allen T. Simmons, president, Box 29, Akron, Ohio.

Station WAIU, 500 watts, clear; Eric S. Howlett, station manager, Associated Radiocasting Corporation, Columbus, Ohio.

Station WAPI, 5 kilowatts, clear; B. H. Hopson, president, WAPI Broadcasting Corporation, Birmingham, Ala.

Station WBBM, 25 kilowatts, clear; H. Leslie Atlass, WBBM Broadcasting Corporation, 410 North Michigan Avenue, Chicago, Ill.

Station WBBZ, 100 watts, local; C. L. Carrell, manager, Ponca City, Okla.

Station WBCM, 500 watts, regional; Stanley F. Northcott, general manager, James E. Davidson, owner; Hotel Wenonah, Bay City, Mich.

Station WBEN, 1 kilowatt, regional; Edgar H. Twamley, director; WBEN, Inc., Buffalo, N.Y.

Station WBEO, 100 watts, local; Leo G. Brett, manager, Lake Superior Broadcasting Co., Marquette, Mich.

Station WBNX, 250 watts, regional; W. C. Alcorn, vice president, Standard Canill Co., New York, N.Y.

Station WBOW, 110 watts, local; W. K. Behrman, vice president, Banks of Wabash, Inc., Terre Haute, Ind.

Station WBRE, 100 watts, local; Louis G. Baltimore, president, 16 North Main Street, Wilkes-Barre, Pa.

Station WBT, 25 kilowatts, clear; W. A. Schudt, Jr., general manager, WBT, Inc., Charlotte, N.C.

Station WBTM, 100 watts, local; S. C. Ondarcho, general manager, Piedmont Broadcasting Corporation, Danville, Va.

Station WCAE, 1 kilowatt, regional; WCAE, Inc., P.O. Box 1133, Pittsburgh, Pa.

Station WCAH, 500 watts, regional; Fred A. Palmer, general manager, Commercial Radio Service Co., 33 West Spring Street, Columbus, Ohio.

Station ACAO, 250 watts, regional; J. Thomas Lyons, executive vice president, Monumental Radio Co., Baltimore, Md.

Station WCAU, 50 kilowatts, clear; Dr. Leon Levy, president, WCAU Broadcasting Co., Philadelphia, Pa.

Station WCAX, 100 watts, local; H. Nelson Jackson, president, Burlington Daily News, Inc., Burlington, Vt.

Station WCBA, 250 watts, regional; B. Bryan Musselman, owner, Allentown, Pa.

Station WCBM, 100 watts, 250 watts local sunset, local; John Elmer, president, Baltimore Broadcasting Corporation, Baltimore, Md.

Station WCCO, 50 kilowatts, clear; E. H. Gammons, vice president, Northwestern Broadcasting Incorporated, Minneapolis, Minn.

Station WCKY, 5 kilowatts, regional; L. B. Wilson, president, L. B. Wilson, Inc., WCKY Building, Covington, Ky.

Station WCLO, 100 watts, local; H. H. Bliss, president, WCLO Radio Corporation, Janesville, Wis.

Station WCNW, 100 watts, local; L. W. Berne, manager, Arthur Faske, owner, 1525 Pitkin Avenue, Brooklyn, N.Y.

Station WCRW, 100 watts, local; Clinton R. White, owner, 2756 Pine Grove Avenue, Chicago, Ill.

Station WCSH, 1 kilowatt, 2½ kilowatts local sunset, regional; Henry P. Rines, president, Congress Square Hotel Co., Portland, Maine.

Station WDAF, 1 kilowatt, regional; H. Dean Fitzer, director, Kansas City Star Co., Kansas City, Mo.

Station WDAY, 1 kilowatt, regional; E. C. Reineke, manager, WDAY, Inc., Fargo, N.Dak.

Station WDBJ, 500 watts, regional; Junius P. Fishburn, president, Times-World Corporation, Roanoke, Va.

Station WBGY, 1 kilowatt, clear; Dr. George W. Young, owner, 2219 Bryant Avenue, North, Minneapolis, Minn.

Station WDOD, 1 kilowatt, 2½ kilowatts local sunset, regional; N. A. Thomas, president, Wood Broadcasting Corporation, Chattanooga, Tenn.

Station WDRC, 1 kilowatt, regional; F. M. Doolittle, president, WDRC, Inc., 11 Asylum St., Hartford, Conn.

Station WDE, 100 watts, local; James L. Bush, owner, Tuscola, Ill.

Station WEAF, 50 kilowatts, clear; National Broadcasting Co., Inc., 30 Rockefeller Plaza, New York, N.Y.

Station WEAN, 250 watts, 500 watts, local sunset, regional; James Jennison, station supervisor, Shepard Broadcasting Service, Inc., Providence, R.I.

Station WEBC, 1 kilowatt, 2½ kilowatts local sunset, regional; W. C. Bridges, general manager, Head of the Lakes Broadcasting Co., Superior, Wis.

Station WEBQ, 100 watts, local; Inglis M. Taylor, manager, Harrisburg Broadcasting Co., Harrisburg, Ill.

Station WEBR, 100 watts, 250 watts local sunset, local; H. H. Howell, president, Howell Broadcasting Co., Inc., Buffalo, N.Y.

Section WEEI, 1 kilowatt, regional; Joseph B. Groce, head of Public Relations Bureau, Edison Electric Illimination Co. of Boston, Boston, Mass.

Station WEEU, 1 kilowatt, clear; Clifford M. Chafey, president, Berks Broadcasting Co., Reading, Pa.

Station WEHC, 55 watts, regional; John T. Elsroad, manager, Community Broadcasting Corporation, Charlottesville, Va.

Station WELL, 50 watts, local; A. L. Miller, president, Enquirer-News Co., Battle Creek, Mich.

Station WENR, 50 kilowatts, clear; Niles Trammel, vice president, National Broadcasting Co., Inc., Chicago, Ill.

Station WESG, 1 kilowatt, clear; John T. Galkins, vice president, WESG, Inc., Elmira, N.Y.

Station WEVD, 500 watts, regional; Alexander Kahn, vice president, Debs Memorial Radio Fund, Inc., 225 Broadway, New York, N.Y.

Station WFAA, 50 kilowatts, clear; Martin B. Campbell, general Manager, Dallas-News Journal, Dallas, Tex.

Station WFBC, 100 watts, 250 watts local sunset, local; B. H. Peace, Jr., manager, Greenville News-Piedmont Co., Greenville, S.C.

Station WFBG, 100 watts, local; Roy F. Thompson, managing director, Gable Broadcasting Co., Altoona, Pa.

Station WFBL, 1 kilowatt, 2½ kilowatts local sunset, regional; S. Woodworth, general manager, Onondaga Radio Broadcasting Corporation, Syracuse, N.Y.

Station WFBM, 1 kilowatt, regional; R. E. Blossom, manager, Indianapolis Power & Light Co., Indianapolis, Ind.

Station WFBR, 500 watts, regional; Baltimore Radio Shoe Inc., 7 St. Paul Street, Baltimore, Md.

Station WFDF, 100 watts, local; H. M. Loeb, managing director, Flint Broadcasting Co., Flint, Mich.

Station WFI, 500 watts, regional; Ednyfed Lewis, director, WFI Broadcasting Co., Philadelphia, Pa.

Station WFIW, 1 kilowatt, regional; Nathan Lord, secretary-treasurer, WFIW, Inc., Brown Hotel, Louisville, Ky.

Station WGAL, 100 watts, local; I. Z. Buckwalter, treasurer, WGAL, Inc., 8 West King Street, Lancaster, Pa.

Station WGAR, 500 watts, 1 kilowatt local sunset, regional; John F. Patt, president, WGAR Broadcasting Co., Inc., Cleveland, Ohio.

Station WGBF, 500 watts, regional; Clarence Leich, director, Evansville on the Air, Inc., Evansville, Ind.

Station WGBI, 250 watts, regional; Frank Megargee, president, Scranton Broadcasters Inc., Scranton, Pa.

Station WGH, 100 watts, local; Edward E. Bishop, president, Hampton Roads Broadcasting Corporation, Newport News, Va.

Station WGN, 25 kilowatts, clear, Quin A. Ryan, director, WGN, Inc., Chicago, Ill.

Station WGR, 1 kilowatt, regional; I. R. Lounsberry, executive vice president, Buffalo Broadcasting Corporation, Buffalo, N.Y.

Station WHAS, 25 kilowatts, clear; Credo Harris, manager, Louisville Times & Courier Journal Co., Louisville, Ky.

Station WHB, 500 watts, clear; Donald D. Davis, president, WHB Broadcasting Co., Kansas City, Mo.

Station WHBC, 100 watts, local; Rev. E. P. Graham, 319 Tuscarawas Street, West, Canton, Ohio.

Station WHBF, 100 watts, local; James L. Hughes, general manager, Rock Island Broadcasting Co., Rock Island, Ill.

Station WHBL, 500 watts, regional; Press Publishing Co., Sheboygan, Wis.

Station WHBU, 100 watts, local; A. L. McKee, manager, Anderson Broadcasting Corporation, Box 815, Anderson, Ind.

Station WHBY, 100 watts, local; Rev. James A. Wagner, managing director, WHBY, Inc., Green Bay, Wis.

Station WHFC, 100 watts, local; R. W. Hoffman, owner, WHFC, Inc., 6138 West Twenty-second Street, Cicero, Ill.

Station WHK, 1 kilowatt, 2½ kilowatts local sunset, regional; M. A. Howlett, president, Radio Air Service Corporation, Cleveland, Ohio.

Station WHN, 250 watts, regional; George Scoubel, director, Marcus Loew Booking Agency, 1540 Broadway, New York, N.Y.

Station WHOM, 250 watts, regional; Harry F. O'Mealia, president, New Jersey Broadcasting Corporation, 2854 Hudson Boulevard, Jersey City, N.J.

Station WHP, 500 watts, 1 kilowatt local sunset, regional; Edward J. Stackpole, Jr., secretary-treasurer, WHP, Inc., 220 Telegraph Building, Harrisburg, Pa.

Station WIAS, 100 watts, local; Gardner Cowles, Jr., president, Iowa Broadcasting Co., Des Moines, Iowa.

Station WIBA, 500 watts, 1 kilowatt local sunset, W. E. Walker, business manager, Badger Broadcasting Co., Inc., Madison, Wis.

Station WIBM, 100 watts, local; C. A. Hill, manager, WIBM, Inc., Jackson, Mich.

Station WIBW, 1 kilowatt, regional; Don Searle, general manager, Topeka Broadcasting Association, Inc., Topeka, Kans.

Station WICC, 250 watts, 500 watts local sunset, regional; Bridgeport Broadcasting Station, Inc., Bridgeport, Conn.

Station WIL, 200 watts, 250 watts local sunset, local; L. A. Benton, president, Missouri Broadcasting Corporation, St. Louis, Mo.

Station WIND, 1 kilowatt, 1½ kilowatts local sunset, regional; Johnson-Kennedy Radio Corporation, Chicago, Ill.

Station WIP, 500 watts, regional; H. Bart McHugh, Jr., president, Pennsylvania Broadcasting Co., Philadelphia, Pa.

Station WJAC, 100 watts, local; J. C. Tully, manager, WJAC, Inc., Johnstown, Pa.

Station WJAG, 1 kilowatt, clear; Gene Huse, president, Huse Publishing Co., Norfolk, Nebr.

Station WJAR, 250 watts, 500 watts local sunset, regional; Joseph S. Gettler, managing director, the Outlet Co., Providence, R.I.

Station WJAS, 1 kilowatt, 2½ kilowatts local sunset, regional; H. J. Brennen, general manager, Pittsburgh Radio Supply House, Pittsburgh, Pa.

Station WJAY, 500 watts, regional; G. C. Melrose, manager, Cleveland Radio Broadcasting Corporation, Cleveland, Ohio.

Station WJBK, 50 watts, local; James F. Hopkins, manager, James F. Hopkins, Inc., Hotel Fort Shelby, Detroit, Mich.

Station WJDX, 1 kilowatt, regional; W. P. Harris, director, Lamar Life Insurance Co., Jackson, Miss.

Station WJMS, 100 watts, local; N. C. Ruddell, secretary-manager, WJMS, Inc., Ironwood, Mich.

Station WJR, 10 kilowatts, clear; Leo Fitzpatrick, vice president, WJR, the Goodwill Station, Inc., Fisher Building, Detroit, Mich.

Station WJSV, 10 kilowatts, regional; Harry C. Butcher, general manager, Old Dominion Broadcasting Co., Earle Building, Washington, D.C.

Station WJZ, 30 kilowatts, clear; A. L. Ashby, vice president, National Broadcasting Co., Inc., 30 Rockfeller Plaza, New York, N.Y.

Station WKBF, 500 watts, regional; D. E. Kendrick, general manager, Indianapolis Broadcasting Co., Indianapolis, Ind.

Station WKBN, 500 watts, regional; Warren P. Williamson, Jr., president, WKBN Broadcasting Corporation, Youngstown, Ohio.

Station WKJC, 100 watts, local; A. Z. Moore, president, Lancaster Broadcasting Service, Lancaster, Pa.

Station WKRC, 500 watts, 1 kilowatt experimental, regional; E. S. Mittendorf, president, WKRC, Inc., Cincinnati, Ohio.

Station WKY, 1 kilowatt, regional; Edgar T. Bell, business manager, WKY Radiophone Co., Oklahoma City, Okla.

Station WKZO, 1 kilowatt, regional; John E. Fetzer, president, WKZO, Inc., Kalamazoo, Mich.

Station WLAV, 5 kilowatts, regional; J. T. Ward, vice president Life & Casualty Insurance Co., Nashville, Tenn.

Station WLAP, 100 watts, 250 watts, local sunset, local; Charles C. Leonard, secretary-treasurer American Broadcasting Corporation of Kentucky, 1109 Kentucky Home Life Building, Louisville, Ky.

Station WLBF, 100 watts, local; Herbert Hollister, general manager WLBF Broadcasting Co., Huron Building, Kansas City, Kans.

Station WLSW, 500 watts, 1 kilowatt, local sunset, regional; Herluf Provensen, general manager Broadcasters of Pennsylvania, Inc., Lawrence Hotel, Erie, Pa.

Station WLIT, 500 watts, regional; Mrs. A. T. Hild, president Lit Bros. Broadcasting System, Inc., Philadelphia, Pa.

Station WLOE, 100 watts, 250 watts, local sunset, local; William B. Pote, treasurer Boston Broadcasting Co., 21 Beacon Street, Boston, Mass.

Station WLS, 50 kilowatts, clear; Glenn Snyder, station manager Agricultural Broadcasting Co., Agricultural Building, Chicago, Ill.

Station WLTH, 500 watts, regional; S. J. Gallard, president, Voice of Brooklyn, Inc., Brooklyn, N.Y.

Station WLVA, 100 watts, local; Philip P. Allan, secretary-treasurer Lynchburg Broadcasting Corporation, Lynchburg, Va.

Station WLW, 50 kilowatts, clear; John L. Clark, general manager Crosley Radio Corporation, Cincinnati, Ohio.

Station WMAL, 250 watts, 500 watts, local sunset, regional; Kenneth Berkley, manager National Broadcasting Co., Inc., National Press Building, Washington, D.C.

Station WMAQ, 5 kilowatts, clear; National Broadcasting Co., Inc., 222 North Bank Drive, Chicago, Ill.

Station WMAS, 100 watts, local, Albert S. Moffatt, owner WMAS, Inc., 568 Commonwealth Avenue, Boston, Mass.

Station WMAZ, 500 watts, clear, Edward K. Cargill, president, Southeastern Broadcasting Co., Inc., 211 Cotton Avenue, Macon, Ga.

Station WMBC, 100 watts, 250 watts L.S., local, W. W. Gedge, secretary-general manager, Michigan Broadcasting Co., 7310 Woodward Avenue, Detroit, Mich.

Station WMBD, 500 watts, 1 kilowatt L.S., regional, Edgar L. Bill, president, Peoria Broadcasting Co., Peoria, Ill.

Station WMBG, 100 watts, local, Wilbur M. Havens, president, Havens & Martin, Inc., Richmond, Va.

Station WMBQ, 100 watts, local, Paul J. Gollhofer, owner, 95 Leonard Street, Brooklyn, N.Y.

Station WMC, 500 watts, 1 kilowatt L.S., regional, H. W. Slavick, general manager, WMC, Inc., Memphis, Tenn.

Station WMCA, 500 watts, regional, Donald Flamm, president, Knickerbocker Broadcasting Co., Inc., 1697 Broadway, New York, N.Y.

Station WMT, 500 watts, regional, Harry Shaw, president, Waterloo Broadcasting Co., Waterloo, Iowa.

Station WNAC, 1 kilowatt, regional, John Shepard III, president, Shepard Broadcasting Service, Inc., Boston, Mass.

Station WNAX, 1 kilowatt, 2½ kilowatts, L.S., regional, L. C. Morrison, commercial manager, House of Gurney, Inc., Yankton, S.Dak.

Station WNBF, 100 watts, local, C. D. Mastin, manager, Howitt-Wood Radio Co., Inc., Binghamton, N.Y.

Station WNBH, 100 watts, 250 watts L.S., local, Irving Vermilyn, owner, New Bedford Broadcasting Co., New Bedford, Mass.

Station WNBR, 500 watts, regional, Mallory Chamberlin, president, Memphis Broadcasting Co., Inc., Hotel DeVoy, Memphis, Tenn.

Station WOAX, 50 kilowatts, clear, Hugh A. L. Halff, Southern Industries, Inc., San Antonio, Tex.

Station WOC-WHO, 5 kilowatts, clear, J. O. Maland, sales manager, Central Broadcasting Co., Des Moines, Iowa.

Station WOKO, 500 watts, regional, H. E. Smith, general manager, WOKO, Inc., Ten Eyck Hotel, Albany, N.Y.

Station WOL, 100 watts, local, LeRoy Mark, president, American Broadcasting Co., Annapolis Hotel, Washington, D.C.

Station WOPI, 100 watts, local, W. A. Wilson, vice president, Radiophone Broadcasting Station WOPI, Inc., Bristol, Tenn.

Station WOR, 5 kilowatts, clear, A. J. McCosker, president, Bamberger Broadcasting Service, Inc., 1440 Broadway, New York, N.Y.

Station WORC, 100 watts, local, Alfred F. Kleindienst, owner, 60 Franklin Street, Worcester, Mass.

Station WOW, 1 kilowatt, regional, William Ruess, personal director, Woodmen of the World Life Insurance Association, Omaha, Nebr.

Station WPEN, 100 watts, 250 watts, L.S., local, Paul F. Harron, vice president, Wm. Penn Broadcasting Co., 217 South Broad St., Philadelphia, Pa.

Station WPG, 5 kilowatts, clear, Edwin M. Spence, vice president, WPG Broadcasting Corporation, Atlantic City, N.J.

Station WPRO, 100 watts, local, Paul Cury, station director, Cherry & Webb Broadcasting Corporation, Providence, R.I.

Station WPTF, 1 kilowatt, clear, H. K. Carpenter, manager, WPTF Radio Co., Raleigh, N.C.

Station WQAM, 1 kilowatt, regional, F. W. Borton, president, Miami Broadcasting Co., Inc., Miami, Fla.

Station WRAK, 100 watts, local; Clarence R. Cummins, owner, WRAK, Inc., Williamsport, Pa.

Station WRAM, 100 watts, local; E. W. Carr, vice president, Wilmington Radio Association, Inc., Wilmington, N.C.

Station WRBL, 100 watts, local; David Farmer, director, WRBL Radio Station, Inc., Columbus, Ga.

Station WRC, 500 watts, regional; Frank M. Russell, vice president, National Broadcasting Co., Inc., National Press Building, Washington, D.C.

Station WREC, 500 watts, regional; Hoyt B. Wooten, president, WREC, Inc., Hotel Peabody Building, Memphis, Tenn.

Station WREN, 1 kilowatt, regional; Vernon H. Smith, manager, Jenny Wren Co., Lawrence, Kans.

Station WRJN, 100 watts, local; H. S. Mann, secretary-treasurer, Racine Broadcasting Corporation, Racine, Wis.

Station WRVA, 5 kilowatts, clear; C. T. Lucy, station manager, Larus & Bro. Co., Inc., Richmond, Va.

Station WSAI, 500 watts, regional; John L. Clark, general manager, Crosley Radio Corporation, Cincinnati, Ohio.

Station WSAR, 250 watts, regional; William T. Welch, treasurer, Doughty & Welch Electric Co., Inc., 10 Bedford Street, Fall River, Mass.

Station WSB, 50 kilowatts, clear; Lambdin Kay, director, Atlanta Journal Co., Atlanta, Ga.

Station WSBC, 100 watts, local; F. A. Stanford, managing director WSBC, Inc., Hotel Crillon, Chicago, Ill.

Station WSFA, 500 watts, regional; S. G. Persons, president Montgomery Broadcasting Co., Inc., Montgomery, Ala.

Station WSM, 50 kilowatts, clear; C. R. Clements, vice president National Life & Accident Insurance Co., Nashville, Tenn.

Station WSMB, 500 watts, regional; H. Wheelahan, manager WSMB, Inc., New Orleans, La.

Station WSOC, 100 watts, local; R. S. Morris, secretary WSOC, Inc., Charlotte, N.C.

Station WSPD, 1 kilowatt, regional; J. H. Ryan, vice president Toledo Broadcasting Co., Toledo, Ohio.

Station WSUN, 250 watts, Station WFLA, 500 watts local sunset, regional; Carl Fritz, director, city of St. Petersburg, City Hall, St. Petersburg, Fla.

Station WTAG, 250 watts, 500 watts local sunset, regional; J. J. Storey, general manager Worcester Telegram Publishing Co., Inc., Worcester, Mass.

Station WTAM, 50 kilowatts, clear; W. W. Smith, manager National Broadcasting Co., Inc., Cleveland, Ohio.

Station WTAX, 100 watts, local; J. A. Johnson, president WTAX, Inc., 416 East Capitol Avenue, Springfield, Ill.

Station WTIC, 50 kilowatts, clear; Paul W. Morency, general manager Travelers Insurance Co., Hartford, Conn.

Station WTMJ, 1 kilowatt, 2½ kilowatts local sunset, regional; Walter J. Damm, promotion manager Milwaukee Journal Co., Milwaukee, Wis.

Station WTOC, 500 watts, regional; W. T. Knight, Jr., president Savannah Broadcasting Co., Inc., Savannah, Ga.

Station WTRC, 100 watts, local; R. R. Baker, manager Truth Radio Corporation, Elkhart, Ind.

Station WWJ, 1 kilowatt, regional; J. B. Webb, manager Evening News Association, Inc., Detroit, Mich.

Station WWL, 10 kilowatts, clear; Rev. W. A. Burke, Loyola University, Roosevelt Hotel, New Orleans, La.

Station WWRL, 100 watts, local; William H. Reuman, president Long Island Broadcasting Corporation, Woodside, N.Y.

Station WXYZ, 1 kilowatt, regional; George W. Treadle, president and general manager Kinsky-Treadle Broadcasting Corporation, Detroit, Mich.

Station KBTM, 100 watts, local; Jay P. Beard, manager Beard's Temple of Music, Paragould, Ark.

Station KCMC, 100 watts, local; M. P. Mims, general manager North Mississippi Broadcasting Corporation, Texarkana, Ark.

Station KDB, 100 watts, local; Frank C. McBride, manager Santa Barbara Broadcastings, Ld., Santa Barbara, Calif.

Station KDFN, 500 watts, regional; Donald L. Hathaway, owner, Casper, Wyo.

Station KDKA, 50 kilowatts, clear; William S. Hedges, general manager National Broadcasting Co., Inc., William Penn Hotel, Pittsburgh, Pa.

Station KDLR, 100 watts, local; Bert Wick, director KDLR, Inc., Devils Lake, N.Dak.

Station KDYL, 1 kilowatt, regional; Philip G. Lasky, director Intermountain Broadcasting Corporation, Salt Lake City, Utah.

Station KECA, 1 kilowatt, regional; Arthur F. Kales, station manager Earle C. Anthony, Inc., 1000 South Hope Street, Los Angeles, Calif.

Station KERN, 100 watts, local; Norman McLaughlin, manager Bee Bakersfield Broadcasting Co., Bakersfield, Calif.

Station KFAB, 5 kilowatts, clear; Dietrich Dirks, station director KFAB Broadcasting Co., Lincoln, Nebr.

Station KFBB, 1 kilowatt, 2½ kilowatts, local sunset, regional; Mrs. Jessie Jacobson, manager Buttrey Broadcast, Inc., Great Falls, Mont.

Station KFBK, 100 watts, local; G. C. Hamilton, business manager James McClatchy Co., Sacramento, Calif.

Station KFEL, 500 watts, regional; Eugene P. O'Fallon, president, Eugene P. O'Fallon, Inc., Denver, Colo.

Station KFI, 50 kilowatts, clear; Earle C. Anthony, president, Earle C. Anthony, Inc., Los Angeles, Calif.

Station KFJR, 500 watts, regional; Ashley C. Dixon, president, KFJR, Inc., Portland, Oreg.

Station KFJZ, 100 watts, local; R. S. Bishop, president, Fort Worth Broadcasters, Inc., Fort Worth, Tex.

Station KFKA, 500 watts, 1 kilowatt local sunset, regional; H. E. Green, managing director, Mid-Western Radio Corporation, 620 Eight Avenue, Greeley, Colo.

Station KFNF, 500 watts, 1 kilowatt local sunset, regional; F. E. Tunnicliff, treasurer, Henry Field Co., Shenandoah, Iowa.

Station KFPL, 100 watts, local; C. C. Baxter, director, KFPL Broadcasting Station, Dublin, Tex.

Station KFPW, 100 watts, local; John A. England, manager, Southwestern Hotel Co., Fort Smith, Ark.

Station KFPY, 1 kilowatt, regional; T. W. Symons, Jr., president, Symons Broadcasting Co., Spokane, Wash.

Station KFRC, 1 kilowatt, regional; Harrison Holliway, manager, Don Lee Broadcasting System, 1000 Van Ness Avenue, San Francisco, Calif.

Station KFSD, 1 kilowatt, regional; Thomas E. Sharp, Airfan Radio Corporation, San Diego, Calif.

Station KFVD, 250 watts, clear; George L. Moskovics, general manager, Los Angeles Broadcasting Co., Inc., 645 South Mariposa Avenue, Los Angeles, Calif.

Station KFVS, 100 watts, local; Oscar C. Hirsch, manager, Hirsch Battery & Radio Co., Cape Girardeau, Mo.

Station KFWB, 1 kilowatt, regional; Gerald King, manager, Warner Bros. Broadcasting Corporation, Los Angeles, Calif.

Station KFYO, 100 watts, 250 watts, local sunet, local; T. W. Kirksey, director, Lubbock, Tex.

Station KFYR, 1 kilowatt, 2½ kilowatts local sunset, regional, P. J. Meyer, president, Meyer Broadcasting Co., Bismarck, N.Dak.

Station KGA, 5 kilowatts, regional; H. I. Milholland, manager, Northwest Broadcasting System, Inc., Spokane, Wash.

Station KGB, 1 kilowatt, regional; Lincoln Dollar, manager, Don Lee Broadcasting System, 112 First Street, San Diego, Calif.
Station KGBX, 100 watts, local; R. D. Foster, president, KGBX, Inc., Springfield, Mo.
Station KGCK, 100 watts, local; E. E. Krebsbach, manager, Wolf Point, Mont.
Station KGEZ, 100 watts, local; Donald C. Treloar, manager, Kalispell, Mont.
Station KGFJ, 100 watts, local; Ben S. McGlashan, manager, 1417 South Figueroa Street, Los Angeles, Calif.
Station KGFK, 100 watts, local; C. E. Kistler, manager, Red River Broadcasting Co., Inc., Moorhead, Minn.
Station KGFW, 100 watts, local; Charles R. Wareham, manager, Central Nebraska Broadcasting Corporation, Kearney, Nebr.
Station KGGC, 100 watts, local; W. N. McGill, general manager, Golden Gate Broadcasting Co., San Francisco, Calif.
Station KGGF, 500 watts, 1 kilowatt local sunset, regional; Hugh J. Powell, manager, Powell & Platz, Coffeyville, Kans.
Station KGHL, 1 kilowatt, 2½ kilowatts local sunset, regional; C. O. Campbell, vice president, Northwestern Auto Supply Co., Inc., Billings, Mont.
Station KGIR, 500 watts, 1 kilowatt local sunset, regional; E. B. Craney, manager, KGIR, Inc., Butte, Mont.
Station KGMB, 250 watts, regional; A. Henley, general manager, Honolulu Broadcasting Co., Ltd., 119 Marchant Street, Honolulu, T. H.
Station KGO, 7½ kilowatts, clear; Don E. Gilman, vice president, National Broadcasting Co., Inc., 111 Sutter Street, San Francisco, Calif.
Station KGRS, 1 kilowatt, regional; E. B. Gish, owner, Gish Radio Service, Bellaire Park, Amarillo, Tex.
Station KGVO, 100 watts, local; A. J. Mosby, manager, Mosby's, Inc., 240 North Higgins Street, Missoula, Mont.
Station KGW, 1 kilowatt, regional; C. O. Chatterton, business manager, Oregonian Publishing Co., Portland, Oreg.
Station KHJ, 1 kilowatt, regional; W. J. Gleason, Don Lee Broadcasting System, Seventy-fifth at Bixel Street, Los Angeles, Calif.
Station KHQ, 1 kilowatt, 2 kilowatts local sunset, regional; Louis Wasmer, president Louis Wasmer, Inc., Spokane, Wash.
Station KID, 250 watts, 500 watts local sunset, regional; Jack W. Duckworth, president Kid Broadcasting Co., Inc., Idaho Falls, Idaho.
Station KJBS, 100 watts, clear; Ralph R. Brunton, general manager Julius Brunton & Sons Co., San Francisco, Calif.
Station KLUF, 100 watts, local; George Roy Clough, owner, Galveston, Tex.
Station KLZ, 1 kilowatt, regional; F. W. Meyer, Reynolds Radio Co., Inc., Denver, Colo.
Station KMAC, 100 watts, local; Howard W. Davis, manager, W. W. McAllister, owner, San Antonio, Tex.
Station KMBC, 1 kilowatt, regional; Arthur B. Church, vice president Midland Broadcasting Co., Kansas City, Mo.
Station KMED, 100 watts, local; Mrs. W. J. Virgin, manager Virgin's Broadcasting station, Medford, Oreg.
Station KMJ, 500 watts, regional; Ed S. Riggins, business manager James McClatchy Co., Fresno, Calif.
Station KMOX, 50 kilowatts, clear; J. L. Van Volkenburg, director of sales, Voice of St. Louis, Inc., St. Louis, Mo.
Station KOIL, 1 kilowatt, regional; John Henry, president Mona Motor Oil Co., Council Bluffs, Iowa.
Station KOIN, 1 kilowatt, regional; C. R. Hunt, general manager Koin, Inc., Portland, Oreg.
Station KOL, 1 kilowatt, regional; Archie Taft, Seattle Broadcasting Co., Inc., Seattle, Wash.
Station KOMO, 1 kilowatt, regional; Birt F. Fisher, business manager Fisher's Blend Station, Inc., Seattle, Wash.
Station KPO, 50 kilowatts, clear; Don E. Gilman, vice president National Broadcasting Co., Inc., San Francisco, Calif.
Station KPQ, 100 watts, local; Cole E. Wylie, manager Wescoast Broadcasting Co., Wenatchee, Wash.
Station KPRC, 1 kilowatt, 2½ kilowatts, local sunset, regional; G. E. Zimmerman, general manager Houston Printing Co., Houston, Tex.
Station KQV, 500 watts, regional; Kov Broadcasting Co., Pittsburgh, Pa.
Station KRSC, 100 watts, regional; Robert E. Priebe, manager Radio Sales Corporation, Seattle, Wash.

Station KSD, 500 watts, regional; William H. West, the Pulitzer Publishing Co., Twelfth and Olive Streets, St. Louis, Mo.
Station KSEI, 250 watts, 500 watts, local sunset, regional; Robert E. Lee, Jr., general manager Radio Service Corporation, Pocatello, Idaho.
Station KSL, 50 kilowatts, clear; Earl J. Glade, managing director Radio Service Corporation of Utah, Salt Lake City, Utah.
Station KSO, 100 watts, 250 watts, local sunset, local; James C. Hanrahan, executive vice president Iowa Broadcasting Co., Des Moines, Iowa.
Station KSOO, 2½ kilowatts, clear; Joseph Henkin, manager Sioux Falls Broadcasting Association, Sioux Falls, S.Dak.
Station KSTP, 10 kilowatts, 25 kilowatts, local sunset, experimental, regional; Stanley E. Hubbard, vice president National Battery Broadcasting Co., St. Paul, Minn.
Station KTAB, 1 kilowatt, regional; Bob Roberts, general manager Associated Broadcasters, Inc., San Francisco, Calif.
Station KTAR, 500 watts, 1 kilowatt, local sunset, regional; Richard O. Lewis, general manager Ktar Broadcasting Co., Phoenix, Ariz.
Station KTBS, 1 kilowatt, regional; F. H. Ford, president, Tri-State Broadcasting System, Inc., post office box 1642, Shreveport, La.
Station KUJ, 100 watts, local; H. E. Studebaker, manager KUJ, Inc., Walla Walla, Wash.
Station KVOO, 5 kilowatts, clear; William B. Way, general manager Southwestern Sales Corporation, Tulsa, Okla.
Station KVOS, 100 watts, local; KVOS, Inc., Bellingham, Wash.
Station KWCR, 100 watts 250 W.LS, local; S. D. Quarton, president, Cedar Rapids Broadcast Co., Cedar Rapids, Iowa.
Station KWG, 100 watts, local, Bernard Cooney, manager, Portable Wireless Telephone Co., Inc., Stockton, Calif.
Station KWK, 1 kilowatt, regional; Thomas P. Convay, president, Thomas Patrick (Inc.), St. Louis, Mo.
Station KWWG, 500 watts, regional, Frank P. Jackson, manager, 11th & Levee Streets, Brownsville, Tex.

Active Members Affiliated with the Broadcasting Industry but not Owning or Operating Stations

Electrical Research Products Inc., 250 West Fifty-seventh Street, New York, N.Y.
Jansky & Bailey, 922 National Press Building, Washington, D.C.
M. A. Leese, 614 Ninth Street, NW., Washington D.C.
John V. L. Hogan, President, Radio Station WQXR, Radio Pictures, Inc., 41 Park Row, New York, N.Y.
Harry Sadenwater, manager, Engineering Products Division, R.C.A.—Victor Company, Inc.
P. L. Thomson, director of public relations, Western Electric Co., 195 Broadway, New York, N.Y.
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List of Associate Members of the National Association of Broadcasters

Station WAWZ, 250 watts, regional; Ray B. White, Pillar of Fire, Zarephath, N.J.
Station WCAL, 1 kilowatt, regional; M. C. Jensen, manager, St. Olaf College, Northfield, Minn.
Station WCAO, 500 watts, regional; Pensacola Broadcasting Co., Pensacola, Fla.
Station WEW, 1 kilowatt, day; George Rueppel, manager, St. Louis University, St. Louis, Mo.
Station WHAD, 250 watts, regional; A. H. Poetker, Director, Marquette University, Milwaukee, Wis.
Station WILL, 250 watts, 1 kilowatt LS, regional; Josef A. Wright, University of Illinois, Urbana, Ill.
Station WKAR, 1 kilowatt, day; P. J. Baldwin, chairman supervision committee, Michigan State College, East Lansing, Mich.
Station WLB, 1 kilowatt, regional; University of Minnesota, Minneapolis, Minn.

Station WMBI, 5 kilowatts, clear; H. C. Crowell, manager, Moody Bible Institute Radio Station, Chicago, Ill.
Station WOI, 5 kilowatts, clear; W. I. Griffith, manager, Iowa State College of Agriculture & Mechanic Arts, Ames, Iowa.
Station WOS, 500 watts, regional; Pem Gordon, Missouri State Highway Patrol, Jefferson City, Mo.
Station WOSU, 750 watts, 1 kilowatt LS, regional; R. C. Higgy, director, Ohio State University, Columbus, Ohio.
Station WRUF, 5 kilowatts, clear; Garland Powell, director, University of Florida, Gainesville, Fla.
Station WSUI, 500 watts, regional; State University of Iowa, Iowa City, Iowa.
Station WTAW, 500 watts, regional; F. C. Bolton, director, Agricultural and Mechanical College of Texas, College Station, Tex.
Station KFGQ, 100 watts, local; J. C. Crawford, Boone Biblical College, Boone, Iowa.
Station KFKU, 500 watts, regional; Harold Ingham, University of Kansas, Lawrence, Kans.
Station KFSG, 500 watts, regional; Maurice E. Kennedy, Echo Park Evangelistic Association, Los Angeles, Calif.
Station KFUO, 500 watts, regional; Rev. R. Kretzschmar, chairman, Board of Control, Concordia Theological Seminary, St. Louis, Mo.
Station KOAC, 1 kilowatt, regional; W. L. Kadderly, Oregon State Agricultural College, Corvallis, Oreg.
Station KPOF, 500 watts, regional; Ray B. White, Pillar of Fire, Denver, Colo.
Station KUSD, 500 watts, regional; University of South Dakota, electrical engineering department, Vermillion, S.Dak.
Station KWSC, 1 kilowatt, 2 kilowatts LS, regional; F. F. Nalder, State College of Washington, Pullman, Wash.

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STATEMENT OF DR. D. AITCHISON, PRESIDENT, NATIONAL LIBERTIES ASSOCIATION

Dr. AITCHISON. The drug bill presented by Senator Copeland is one of the most diabolical bills ever laid before Congress. It makes Uncle Sam a thief and a criminal. It robs man of ownership. Communism is the outstanding feature.

Remember a formula is an invention, and no man or set of men has any legal right to that formula.

The history of science has clearly proven that the so-called leaders in science have always denounced the greatest formulas.

Dr. Harvey demonstrated to the scientific world the functions of the blood. The allopathic medical trust denounced him as a quack.

Every school child, today, knows that Dr. Harvey was right. Thousands of instances can be cited to prove that the would-be leaders in medicine have been the greatest hindrance to the advancement of true medical science.

Look how the chiropractors, naturipaths, and homeopaths were and are regarded as fakers by the allopathic medical trust.

After the medical trust has doped, butchered, and robbed the millions of victims, then left them as incurable, these noble professions have restored tens of thousands to health.

Gentlemen, do you think it fair, as legal, to compel a person to be actually robbed of his personal property, and by a set of men who hate him, and all decisions would be based on prejudice?

If such a bill were to go through it would deprive the public of medicines of great value.

I cannot imagine a committee that would have the nerve to pass such a bill. But I can see how a man who is already linked up with the medical trust that he would advocate anything to further the ends of the trust that is greasing his palm with blood-soaked dollars, dollars that have been bled from the victims of the allopathic trust.

The bill should read:

All drugs that have been found to be habit-forming, and certain drugs that have a marked injurious effect on the body tissue, the name and percent of such drugs must be on the label.

Then the public would be protected, and also the rights of the manufacturers.

Listen, 90 percent of the drug addicts have been produced by the allopathic prescription medicine. As one of their members said, that the medical trust has been a curse to humanity, and has been actually the primary cause for the increase of suffering.

Statistics prove that thousands of soldiers have been murdered by serums and vaccines, also tens of thousands of children of which the public are not acquainted of the appalling fact.

Gentlemen, I appeal to you to denounce in severest terms the bill presented by Senator Copeland.

I represent approximately forty thousand American people who are opposed to such an infernal concoction, a criminal infringement on the rights of the American public.

(Thereupon, at 7:17 p.m., an adjournment was taken until Friday morning, Dec. 8, 1933, at 10 o'clock.)

FOOD, DRUGS, AND COSMETICS

FRIDAY, DECEMBER 8, 1933

UNITED STATES SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to adjournment, in room 335, Senate Office Building, at 10 a.m., Senator Royal S. Copeland presiding.

Present: Senators Copeland, McNary, and Caraway.

Senator COPELAND. The committee will be in order. We have a great many requests from members of the audience, persons who wish to be heard, and I would like to say a word or two about that before we begin. Bear in mind that this is a hearing. This subcommittee cannot settle anything. It can simply prepare a bill to be sent to the full committee, and then it goes to the Senate. We heard yesterday at great length an explanation of the bill. We heard at almost as great length a constructive criticism of the bill.

We have here five groups represented: Food, cosmetics, newspaper and advertising, including broadcasting, drugs and chemicals. Then we have the consumers, because bear in mind that the purpose of this bill, after all, is to protect the public. Let us not forget that in our debates. It is not alone what we can do to help the commercial industry, but what we can do to protect the public against foods and drugs of doubtful propriety.

A great many persons who desire to add to the value of the record wish to present briefs. We hope that desire will become contagious. Bear in mind, too, that if you have occasion in thinking over the hearings to recall things that you wish might have been added to the record, you may send forward to the committee any information in the form of briefs.

Now, I am going to ask those who wish to be recorded as present and to file briefs to submit their names.

(The following parties announced their desire to submit briefs:)

W. A. Hines, of Marlow & Hines, attorneys, New York City, Harriet Hubbard Ayer, Inc.

Charles T. Stout, the Delson Chemical Co.

James W. Baldwin, National Association of Broadcasters.

Horace W. Bigelow, American Drug Manufacturers.

John H. Hayes, the Chesebrough Manufacturing Co.; also Stanco Ink; Daggett & Ramsdell; and Jane Arden.

Bonnie L. Fisher, Coast to Coast Health School.

Hugo Mock, American Manufacturers of Toilet Articles.

Donald J. Burke, George H. Lee Co., of Omaha, Nebr.

Eugene C. Brokmeyer, general counsel, International Beauty and Barbers Supply Dealers Association.

R. J. Everett, American Social Hygiene Association.
James W. Waldron, National Association of Druggists.
Dr. Kendall Emerson, National Tuberculosis Association and American Health Association.
Mr. Samuel Fraser, National Apples Association.
The Pacific Coast, California, and Oregon Fruit Growers Association.

Senator COPELAND. This does not preclude anybody else sending forward briefs or sending them later to the committee. They will be incorporated in the record.

Mr. Sebastain Mueller, vice president of H. J. Heinz Co., desires to have a few minutes to present the views of that company with respect to this bill.

STATEMENT OF SEBASTIAN MUELLER, VICE PRESIDENT, H. J. HEINZ CO., PITTSBURGH, PA.

Mr. MUELLER. Mr. Chairman, I am vice president in charge of the manufacturing operations of H. J. Heinz Co., Pittsburgh, Pa.

While in our opinion some minor changes in the bill as written are desirable, we wish to go on record as being in favor of some legislation of this nature. It is our feeling that the bill as drawn is not impracticable and unreasonable, because its enactment in its present form would not necessitate any changes in any of our present manufacturing practices.

However, as we view the situation, we would prefer to have a separate bill drawn to apply to food only as we feel it would be a distinct advantage to the food industry to do so. This industry is certainly large enough to deserve such special consideration, and many of its problems are quite foreign and distinct from those of the drug and cosmetic industries.

Our specific objections to the proposed bill are as follows:

First. Section 3, paragraph (d). We feel the use of any artificial coloring in ordinary food products is objectionable and should be prohibited. In it are the possibilities of the greatest deception. It would be a backward step. If custom and practice seem to require the use of such artificial coloring matter in confectionery or some other special line, where the public expects it, exception might be made to cover such usage.

Senator COPELAND. Would you absolutely exclude the coloring matter?

Mr. MUELLER. Only in food products that have no color. I have a suggested amendment here for that. That paragraph should read:

> A food shall be deemed to be adulterated if it contains any artificial colors except those foods which have no distinctive color such as candies, confections, ices, delicacies, and desserts, and which are expected by the consumer to be artificially colored or tinted. In the case of these exceptions, only such colors should be used as are determined by acknowledged authority to be harmless.

Second, section 11, insofar as this section refers to standards of quality. We manufacture only prepared food products in which flavor is the most outstanding quality factor. Our products do not lend themselves to fixed standards of quality, so we are not in favor of such a provision.

Senator COPELAND. Would you favor the omission of the whole section?

Mr. MUELLER. I would suggest striking out the words "standards of quality."

Senator COPELAND. In section 11, lines 13 and 14, you would strike out "standards of quality"? Is that right?

Mr. MUELLER. Yes, sir.

Third. Section 13. Because the power granted is too broad. While we welcome any inspection of premises, finished or unfinished materials, containers or labels, we object strenuously to inspection of methods and processes unless there is a definite need for such inspection because of some unusual occurrence where the public welfare demands such action. To empower any Federal inspector, and any local or State health officer working under this proposed law free access to methods and processes at any and all times would be most unfair to the industry and would not serve any public interest.

Senator COPELAND. Your idea is that in an emergency where public health is involved that might be done, but in general you would not suggest that.

Mr. MUELLER. Exactly. I also suggest to strike out the words "methods, processes", and to add to line 24, "to inspect methods and processes if sufficient evidence is available to prove such inspection necessary to safeguard public health."

Senator COPELAND. Thank you very much, Mr. Mueller. That will be incorporated into the record. I am going to ask the secretary to take a watch and at the end of 15 minutes to indicate by a stroke of the gavel that that amount of time has been exhausted.

I call now on Mr. Charles Wesley Dunn, general counsel for the Associated Grocery Manufacturers of America, and the American Pharmaceutical Manufacturers Association.

STATEMENT OF CHARLES WESLEY DUNN, GENERAL COUNSEL FOR THE ASSOCIATED GROCERY MANUFACTURERS OF AMERICA, INC., AND AMERICAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Mr. DUNN. Mr. Chairman, the Associated Grocery Manufacturers of America, Inc., the leading food manufacturers, and also a representative group of the food manufacturers of this country, is the nearest thing we have in this country to being a national association of food manufacturers.

The American Pharmaceutical Manufacturers Association includes manufacturers of ethical pharmaceutical products which are sold for use under the physician's direction.

I also desire to appear at this time on my own behalf as one who has given specialized professional consideration to this law for approximately a quarter of a century.

Mr. Campbell is undoubtedly right in his major premise upon which this bill is based, that the Federal Food and Drugs Act requires revision to cure serious defects in it which are derogatory to the public interests.

The act when it was passed in 1906 was defective. Its defective form arose out of two facts. The first was that it was a compromise bill. The second was that it was new legislation, broadly speaking, from the Federal standpoint.

During the consideration of the Federal Food and Drugs Act in Congress—and such legislation was considered beginning with 1879 and continuing to 1906—it was very controversial legislation; and then, aside from the controversy as to whether or not there should be such a law, there was a very great controversy as to what the terms of the law should be. This latter controversy involved an indefinite difference of opinion. So when the law was enacted in 1906 it was seriously defective in form, and the seriousness of its enforcement has amply demonstrated that the act contains other defects which require amendment.

So it is not unnatural that in the 27 years of the life of this act it has been amended five times, and numerous other amendments have been proposed to Congress and are now pending before Congress. Hence the legitimate food and drug manufacturing industry of this country must take the sound position that the act does require certain constructive revision, and that the only objection that can be properly offered to this bill is to the question of its form, where that form is objectionable. There can be no objection, as I say, to the major provisions against false advertising, filled containers, and so forth. The objection as to form falls into two classes—first, the objection against unduly broad or indefinite language; and, secondly, an objection against provisions which are unsound in principle and public policy as such.

I am not going to undertake to analyze the act at this time extensively because, Mr. Chairman, you have stated that you desire to conclude this hearing today and you prefer to have specific amendments and specific objections filed in written form. Therefore, I will cite two illustrations at this time of the objections that we have in mind. First, as to an objection against the form of this bill upon the ground that it is unduly broad.

I will cite as my illustration section 9 (a) on page 12. That section relates to false advertising and defines it as a duplicate of section 6 (a) in respect to the label. This section and section 6 (a) provide, in effect, that a food or a drug or a cosmetic is misbranded or falsely advertised if its label or advertisement or ambiguity or inference creates a misleading impression regarding the product.

My objection, and the objections of the industries that I represent, center around that word "impression." An impression is a state of mind, or a reaction, or a feeling, on the part of the purchaser which may be wholly apart from the facts of the advertisement or the label; any purchaser may have an impression, a misleading impression, regarding a product which arises solely out of his own ignorance or his own stupidity or his own misunderstanding or his own misreading, or whatever the situation may be, wholly apart from the fact as to whether or not the label or advertisement is false in fact. So that as a result of this bill in its present form, the Government would be empowered to condemn a food label, or a food advertisement, or a drug label, or a drug advertisement, upon the ground that it created a misleading impression in the mind of the consumer and regardless of the fact that the label or the advertisement might be wholly true in fact.

Let me give an illustration. You may get the impression for some reason that I am a thief. Whatever the reason for that impression may be, let us assume that it is an entirely erroneous impression.

Upon the theory of this bill I could be put in jail because of your impression. Now, it is perfectly obvious that I should not be condemned for violating a law against thieving unless it is proven in fact that I have stolen. That little illustration goes to the point of our objection against this bill.

We believe the provision here as to both the label and the advertisement should be written in somewhat this form: That a label or an advertisement is false if it is false or injuriously misleading in fact in any material particular relating to the purposes of the act. That is a sound public policy and a sound declaration which is entirely equitable, so far as the industry is concerned, and amply answers the public need against false advertising and false labeling.

Senator COPELAND. Turn to section 6 (a), page 6, for a moment, Mr. Dunn. Suppose that line 24 were changed so that the whole subsection (a) would read: "If its labeling is in any particular false, or no unsupported claims are advanced."

Mr. DUNN. I feel, Mr. Chairman, that that is not, perhaps, the best form of a statement of public policy for this law. The present law provides against a false or misleading label in any particular. That law has been in force for some 27 years with satisfaction in that respect.

Senator COPELAND. Then you would be satisfied to use the language of the present act in the light of the decision that the court made regarding it?

Mr. DUNN. I believe, Senator Copeland, that so far as false advertising is concerned, the amendment should run somewhat in this fashion; should condemn an advertisement as false where it is false or injuriously misleading in a material particular relating to the purposes of the act.

Of course, if this is a material particular it should not be considered. If it is not related to the purposes of the act it should not be considered. But if this touches in fact the consuming public of this country it should be condemned.

Those are sound principles of food and drug law control which have been laid down for years in this country.

Now, I go to the second broad objection against this bill, namely, the insertion of provisions which are unsound in principle and public policy in our view, and I will cite an as illustration of our objection the provision which runs throughout this bill from start to finish giving the Secretary of Agriculture practically unlimited administrative power which has the full force and effect of law.

Now, that provision reverses completely the public policy of the present act and, broadly speaking, reverses the public policy of the food and drugs law of this country as it has existed down to this time. It also is directly contrary to the public policy expressed by the British Food and Drugs Act and the Canadian Food and Drugs Act. For example, the public policy of the present act is substantially this: To set up a general requirement in the act with which the manufacturer must comply; and, on the other hand, to give the Secretary of Agriculture administrative power to enforce that requirement; but when he comes into court the burden of proof is upon the Government to establish that the law has been violated. That is the present public policy of the present act and it is the public policy that has existed

from the very beginning with respect to the food and drugs law of this country, generally speaking.

The public policy of the proposed bill is just the reverse of that. It is to give the Secretary the power broadly to make administrative findings and decisions in the administration of the act, which findings and decisions shall have the force and effect of law. So that when a manufacturer or other person who is charged with the violation of this law goes to court, instead of the burden of proof being upon the Government to establish that he has violated the statute, according to the rules of evidence, he is faced with the situation where the burden of proof is upon him to establish that the administrative decision or finding of fact is wrong.

Now, the decisions of the United States Supreme Court have very broadly sustained administrative power with respect to decisions and findings of fact; and it is almost impossible, in a practical sense, broadly speaking, to everywhere get those administrative decisions and findings under a broad statutory power.

So that the effect of the whole thing with respect to this provision is to substitute the opinion of the Secretary of Agriculture for the judgment of the court or the jury in the final analysis.

We believe that is a fundamentally unsound public policy; that it is not consistent with the principles of the common law, with the principles of the law as it has been developed in this country, and that it is not a proper provision to write into this act.

I am going to confine myself to those two illustrations or objections, and then I ask your permission to file a brief stating specifically our objections with respect to this bill.

I think I expressed the opinion of the legitimate food-manufacturing and drug-manufacturing industries of the country when I say that it is our duty at this time to constructively cooperate with the committee and with the Government to revise this bill, simply to make its form sound, and at the same time to preserve its high purposes of protecting the public health and safeguarding the public health from injurious foods and drugs.

The following resolutions were adopted by the Associated Grocery Manufacturers of America, Inc., and the American Pharmaceutical Manufacturers' Association with reference to this bill:

Resolved, By the Board of Directors of the Associated Grocery Manufacturers of America, Inc., on this 27th day of November 1933, in pursuance of the recommendation by the association's legislative committee, that:

(1) The board approves a sound and constructive revision of the Federal Food and Drugs Act, to correct its defects and to effectually realize its high protective purpose.

(2) The board disapproves S. 1944, because and to the extent it is not drawn in due form to accomplish such a revision of that act.

(3) The board approves action by the association to secure an effective substitute bill, drawn in due form and to be submitted to the board for review.

Resolved, That the American Pharmaceutical Manufacturers' Association in convention assembled on this 10th day of November, 1933, (1) approves a sound, constructive, and early revision of the Federal Food and Drugs Act, to correct its defects and to adequately realize its high intendment of public protection; (2) approves the purpose of the so-called "Tugwell bill", to accomplish such a revision of the act; (3) regretfully disapproves the Tugwell bill, because it is not drawn in due form; (4) pledges its immediate action to suggest an effective substitute bill drawn in due form and directed to provide a basis for general concurrence in the circumstances.

Senator COPELAND. Thank you very much, Mr. Dunn. We shall be glad to have your brief. We have some 2-minute speakers. The next speaker will be Mr. Francis L. Whitmarsh, of the National Wholesale Grocers' Association.

STATEMENT OF FRANCIS L. WHITMARSH, CHAIRMAN OF THE PURE FOOD AND LEGISLATIVE COMMITTEE OF THE NATIONAL AMERICAN WHOLESALE GROCERS' ASSOCIATION

Mr. WHITMARSH. Mr. Chairman and members of the committee, I am speaking now as the chairman of the Pure Food and Legislative Committee of the National American Wholesale Grocers' Association. Our association is the result of the union of the old National Wholesale Grocers' Association and the American Wholesale Grocers' Association, brought about, in part, to promote greater cooperation with the Government under the National Industrial Recovery Act.

The first official act of the National Wholesale Grocers' Association, which was organized in 1906, was to communicate to President Theodore Roosevelt and the leaders in Congress its approval of the National Pure Food Law. For more than 26 years we have worked diligently in promoting the enactment of State food laws prohibiting adulteration and misbranding of foods, uniform with the existing Federal Food and Drugs Act.

While we are not here to oppose the underlying principles of this bill, we feel that it would be unfortunate if the present Food and Drugs Act were repealed and an entirely new statute substituted, as is here proposed.

If under the present statute serious abusage exists as respects food products, it is our view that these abuses should be corrected by amending the existing law rather than to discard all that has been accomplished in the way of enforcement and interpretation by the courts during the past quarter of a century.

We are submitting for the record a memorandum indicating our suggestions and requesting various changes in a number of the provisions of the pending measure.

Senator COPELAND. That is, you are recommending changes in the bill that is now before us?

Mr. WHITMARSH. We are recommending that the present existing Pure Food and Drugs Act be amended so as to give sufficient strength rather than an entirely new bill.

Senator COPELAND. Are you making any suggestions as to the amendment of the bill that is now being heard?

Mr. WHITMARSH. In our memorandum we are doing so.

Senator COPELAND. Very well. Thank you.

(The memorandum above referred to is as follows:)

DECEMBER 8, 1933.

MEMORANDUM OF NATIONAL AMERICAN WHOLESALE GROCERS' ASSOCIATION CONCERNING S. 1944

To prevent the manufacture, shipment, and sale of adulterated or misbranded food, drugs, and cosmetics, and to regulate traffic therein; to prevent the false advertisement of food, drugs, and cosmetics, and for other purposes.

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On August 4, 1933, the National Wholesale Grocers' Association and the American Wholesale Grocers' Associatoin were merged at a meeting held in the City of Washington. One of the purposes of this merger was to bring about a united front in the wholesale grocery industry in its operations under the provisions of the National Industrial Recovery Act and the Agricultural Adjustment Act.

The National Wholesale Grocers' Association, one of the constituent organizations in the present merged Association was organized in 1906 prior to the enactment of the original Food and Drugs Act. One of the first official acts of the National Wholsale Grocers' Association was to communicate to President Theodore Roosevelt and the leaders in Congress its endorsement and approval of a pure food law which would afford greater protection to consumers and to honest manufacturers and distributors throughout the country. Following the enactment of the Federal statute and for more than 26 years the National Wholesale Grocers' Association has devoted its efforts to urging enactment of State pure food statutes uniform with the Federal Food and Drugs Act, and as we know, in a vast majority of cases our State food laws are substantially uniform with the Federal Food and Drugs Act. Since its organization, the National Wholesale Grocers' Association consistently and constantly has urged enactment of food laws prohibiting adultoration and misbranding of food, not only in the interest of the consumer but as a protection to the honest manufacturer and distributor against the activities of unscrupulous competitors. So that it truthfully can be said that the National Wholesale Grocers' Association favors enactment and enforcement of pure food laws.

At this point, and in order to clarify the position of the wholesale grocer, it should be said that, while the association never has opposed the enactment of statutes or the adoption of regulations which would prohibit adulteration and misbranding, nevertheless the organization has continued throughout this long period of years to express its opposition to the enactment of measures which would unnecessarily burden the business of the interstate shipper of foods without affording any greater protection to the consuming public.

The present statute enacted in 1906 has been of great benefit to the public and the legitimate honest manufacturer. While the law may have its defects, it has, to a very great extent, eliminated many forms of adulteration and misbranding, and it has succeeded in placing in the hands of the housewife more wholesome food products bearing more honest labels. In the recent report of the Food and Drug Administration it is stated that, since 1906 more than 22,000 actions under the law have been concluded.

In the reports of congressional committees on the original Food and Drugs Act we find that it was one of the principal objects of the bill to prohibit the manufacture of food containing foreign substances poisonous or deleterious to the health of our people. The House committee in its report said:

"The purpose of the pending measures is not to compel people to consume particular kinds of food. It is not to compel manufacturers to produce particular kinds or grades of food." We feel that it is not the intention of the present Congress to compel our people to consume particular kinds of food, nor to compel manufacturers to produce particular kinds or grades of food

While we are not here to object to or oppose the underlying principles of the pending bill, we feel that in many respects the provisions of the measure are vague and indefinite and subject to misinterpretation. Unquestionably, these provisions should be clarified, since the bill deals with a subject of vital interest to the entire Nation. A few illustrations will suffice to make clear what we have in mind:

1. Section 2, (e) defines the term "interstate commerce" to include commerce between any State or territory and any place outside

thereof. This section is an attempt to legislate for the entire world, and it would result in serious loss and damage to producers, packers, and distributors engaged in export trade. Packers and distributors in this country now prepare and label their products to comply with the requirements of the foreign countries to which they ship. If these producers and distributors are to retain such export trade as they now have they must meet requirements of the foreign countries to which they ship their merchandise. We respectfully urge, therefore, that the provisions of the existing statute as respects interstate commerce be retained.

2. Section 3 of the measure provides that a food shall be deemed to be adulterated if it is or may be dangerous to health. We must admit that there are types of wholesome and unadulterated food products which may be dangerous to the "health" of certain individuals, but which are not in any respect "dangerous" insofar as the public health is concerned.

3. Section 6, paragraph (a), provides that food shall be deemed to be misbranded if its label "by ambiguity or inference creates a misleading impression"; and paragraph (c) of the same section provides that food shall be deemed misbranded if any information on the label is not "in such terms as to be readily intelligible to the purchasers and users of such articles under customary conditions of purchase and use." These provisions are entirely too broad, and in numerous instances would require manufacturers and distributors to label their products down to the intelligence (?) of those who might infer anything from a label. We should bear in mind that in certain sections of this country, particularly those that have a very large foreign population, thousands of consumers are unable to read any label printed in the English language.

4. Under the provisions of section 7, paragraph (f), food would be deemed misbranded if it were a product for which no definition of identity had been prescribed, and the label failed to bear the common and usual name of each ingredient thereof in order of predominance by weight. This provision would require many wholesome food products packed under ideal conditions and sold under their own distinctive names to be labeled so as to indicate each ingredient. The effect of this provision would be to require many manufacturers and wholesalers to disclose to competitors the private formula for their products. The provision would absolutely destroy the valuable goodwill built up over a long period of years, and at great expense in many wholesome food products.

5. In section 9, an advertisement of a food product would be deemed to be false if "by ambiguity or inference" it created a misleading impression. We do not in any respect defend false or misleading advertising of any product, yet the provisions of section 9 in this respect are so broad as to restrict the legitimate activities of advertisers to such an extent that they would be compelled, in many cases, to write their advertising down to the intelligence of those who would not be inference get a misleading impression regarding the advertising of the product.

6. Section 11 authorizes the Secretary of Agriculture to fix, establish and promulgate definitions of identity and standards of quality, and fill of container for any product. In this connection, section 7 provides that a food shall be deemed misbranded if it fail to indicate on

the label (if so required by the regulations), a standard of quality in such terms as the regulations may specify.

Here again it must be stated that we hold no brief for stubstandard food products.

The latest expression of Congress as respects food standards is contained in what is known as the McNary-Mapes amendment of the Food and Drugs Act, which authorizes the Secretary of Agriculture to establish a reasonable standard of quality for each class of canned food. This statute specifically provides that "the word 'class' means and is limited to a generic product for which a standard is to be established and does not mean a grade, variety, or species of a generic product."

The subject of standards and grades for food products will be discussed thoroughly by others representing the trade, and we will not review this phase of the subject in this memorandum.

7. Section 12 of the measure provides that whenever the Secretary of Agriculture finds that the distribution in interstate commerce of any class of food may, by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health, he is authorized to require manufacturers, processors, and packers to hold permits. We respectfully urge that this section be so changed as to provide that whenever the Secretary finds that distribution of any product shall be injurious to the public health, he may require permits, etc.

8. Under the provisions of section 17, paragraph (6) (e), no dealer would be prosecuted insofar as penalties are concerned if he could establish a guaranty from the person from whom he received the article of food to the effect that such person assumes full responsibility for any violation of the act.

We respectfully urge that the provisions of section 9 of the existing Federal Food and Drugs Act be retained to the effect that no dealer shall be prosecuted under the provisions of the act when he can establish a guaranty from the seller to the effect that the product is not adulterated or misbranded within the meaning of the act.

9. Section 24 provides that a right of action for damages shall accrue to any person for injury or death proximately caused by violation of the act. This section should be considered in conjunction with section 3, which provides that a food shall be deemed to be adulterated if it may be dangerous to health.

If enacted in this form the bill would encourage and promote what now has become a "racket." Legitimate manufacturers constantly are faced with fraudulent claims of those who allege that they have been injured by consumption of food products, and this section of the bill would result in an increase in these fraud cases. The law as to liability for personal injuries is well settled and established, not only by statute but also by the decisions of the courts.

10. Section 26 of the bill provides that "This act shall take effect 6 months after the date of approval."

Food manufacturers and wholesale grocers purchase many of their products long in evidence of their distribution and sale. Labels, cartons, and other containers are prepared and purchased long in advance of their use. At the present time millions of dollars are invested in the labels, cartons, and other containers of food manufactures and wholesale distributors. Six months' time is wholly

inadequate within which to dispose of food products and labels, cartons, and packages on hand.

When the Gould weight- or measure-branding amendment of the present statute was enacted it specifically allowed, in section 2, 18 months after passage of the statute within which to dispose of merchandise on hand.

We respectfully urge, therefore, that section 26 of the pending bill be amended so as to provide at least 18 months within which to dispose of products on hand.

CONCLUSIONS

Section 26 of the bill would repeal the existing Federal Food and Drugs Act.

The existence of the Federal Food and Drugs Act has been justified not only by the work of the Department of Agriculture in enforcement—22,000 actions concluded since 1906—but also by the vast improvement in the manufacture, distribution, and sale of food products. If, under the present statute, serious abuses exist in the food industry which it is not possible to control surely we should not disregard all that has been accomplished in the way of enforcement and interpretation by the courts since 1906. If amendment of the statute as respects food is necessary, there is no real reason for repealing the entire statute as respects food products.

Senator COPELAND. We will hear now from Dr. John F. Anderson, of the E. R. Squibb & Sons, of New York City.

STATEMENT OF DR. JOHN F. ANDERSON, VICE PRESIDENT OF E. R. SQUIBB & SONS, NEW YORK CITY

Dr. ANDERSON. Mr. Chairman and members of the subcommittee on commerce, my name is John F. Anderson. I am a physician, a vice president of E. R. Squibb & Sons, of New York City, and director of the research and biological laboratories of that company. I appear before this subcommittee to present the results of a careful study and analysis conducted by E. R. Squibb & Sons of the provisions of S. 1944, introduced by Senator Copeland.

E. R. Squibb & Sons are manufacturers of medicinal products, including many important chemical and biological agents, as, for example, ether, insulin, antitoxins, cod liver oil and vitamin concentrates and similar preparations. The company also manufactures so-called "household products and cosmetics" among the more familiar of which are dental cream, shaving cream, and bicarbonate of soda.

Study of the general purposes of the proposed bill as well as of its specific provisions was made in the light of the knowledge and familiarity with the drug industry as a whole which the staff of E. R. Squibb & Sons possesses. As a result of this study, which necessarily involved a consideration of former legislation on these subjects, E. R. Squibb & Sons have reached the definite conclusion that the proposed legislation, in its general purposes as well as in perhaps most of its specific provisions, should be adopted as a measure for the better protection of the public health. We believe, however, that there are certain provisions in the bill as now proposed which are, and can be shown to be, inapt or unnecessary to accomplish the purposes of the bill, and that they should either be removed or altered

to the end that a law capable of enforcement and respected in its observance be enacted.

There have been, and probably always will be, certain abuses in connection with the distribution of drugs and medicinal preparations. The extent of these abuses, however, and the changing conditions surrounding the distribution of these preparations are such that, in our judgment, new and comprehensive legislation should be adopted to limit them. The so-called "Food and Drugs Act of 1906" was the first step in this direction and though it brought great benefits to the public health it is abundantly apparent that additional legislation is now required to deal with matters untouched by that law and to make more effective the administration of the law which appears to us necessary to meet new conditions.

Perhaps the most important single feature in which the proposed legislation varies from the present law is the express limitation of advertising, a subject which is not dealt with in the present law. Many of the vices which the present law tended to correct in respect of labeling have cropped up in the form of general advertising. There would appear to be no sound reason why false or misleading advertising of foods, drugs, and cosmetics should not be covered by law as well as false or misleading labeling, since a campaign of advertising may very readily be designed to supply any lack of claims in the statements contained on the label of a product. Not only are the most extravagant claims being asserted but a type of advertising has grown up built upon the prevalence and consequences of certain diseases whose object has been deliberately to mislead the public into believing the products advertised are cures for such diseases, when in fact their real effect, to say the least, is nil. To a very important extent newspapers and periodicals have been the censors of their own advertising but there are still a number of outlets by which the quack and the fraud can advertise his preparations to the public. Even reputable manufacturers under the stress of competition at times have felt it necessary in order to compete effectively with others, to resort to the use of extravagant, unjustified, or misleading statements respecting their preparations.

Some reasonable limitations and restrictions on this type of advertising could only have a salutary effect. It is therefore our view that is is advisable that some legislation in this field be encated. We therefore suggest only certain comparatively slight modifications in the proposed legislation dealing with advertising which will, we believe, leave the proposed bill free to deal effectively with at least most of the abuses which now exist and at the same time to include nothing which would impair the right of any honest manufacturer to advertise his products fully and fairly.

Before passing to a consideration of the specific provisions of the bill, we think it will be helpful if we refer to certain general matters connected with the bill. The first of these is the suggestion which has been encountered to the effect that it will be more advisable to seek an amendment of the present law rather than to enact an entirely new law. The argument in this regard is not without weight, since it points out that the present law makes provision for the outright repeal of the act of 1906, under which so much progress has been made and under which many helpful interpretative decisions of the courts have been rendered. The present law was itself amended on a number of

occasions and it is not in its present form an entirely cohesive piece of legislation. One would therefore believe that more could be accomplished by enacting an entirely new law, so drafted as to preserve the good features of the present law and those upon which interpretative and helpful decisions have been rendered.

While we have no strong views on this matter, such study as we have made of the present law and the important decisions under it discloses nothing which is not covered or which cannot readily be covered by the Copeland bill or amendments to it and, generally speaking, in a more effective fashion. To a large extent, if not entirely, the effect of the more important decisions under the present law have been written into the proposed law and in some cases we find traces in the proposed bill of the actual language contained in the opinions of the court in cases arising under the present law. Furthermore, the effect of certain undesirable restrictive provisions of and decisions under the present law would be largely avoided if an entirely new law were passed.

There is a further subject which has in some quarters taken the form of an objection to the bill and that is that the bill marks a further attempt to extend Government control over business and to deal with matters which had best be left to State control if any necessity for control exists at all. It is said that by means of the convenient device of referring to the regulation of interstate commerce as well as to the use of the mails, matters which are properly only within the province of the States' authority are being dealt with under Federal laws and the proposed bill is cited as an outstanding example of this tendency. We do not believe that anyone can properly say that the dissemination of foods, drugs, and cosmetics is not a matter over which the Federal Government should exercise itself. It is a national problem and has been recognized as such at least since 1906. However, to insure effective regulation by the National Government, which is absolutely essential if any real results are to be attained, we believe it is the more essential to see that the proposed law is reasonably framed and does not in its attempt to regulate everything, regulate nothing. In our judgment the elimination of certain provisions for factory inspection as well as certain powers proposed to be given to the Secretary of Agriculture to issue regulations with the force of law is necessary if only for the reason that the proposed bill, being thus made less ambitious in its attempt to control so many features of the industries involved, will have the greater support and effect.

There is at present a very important element in the distribution of food and drugs to the public which is not adequately taken care of either by the present law or by the proposed bill and it is one which needs, in our judgment, prompt and effective consideration purely from the point of view of the public health. I refer to the now widespread practice of counterfeiting of food and drug products. Disreputable elements in the drug industry now unhappily recruited to a large extent from or cooperating with the liquor bootlegging industry have been making and distributing to the public in interstate commerce all manner of concoctions under forged and counterfeit labels, an art in which great skill has been attained. There is no supervision of their manufacture, the laws of many States are totally inadequate and unless some Federal legislation is adopted to check these abuses we can only look forward to an increase in this dangerous practice. The

Government has heretofore been reluctant, largely on account of limited appropriations, to assist legitimate manufacturers in fighting these practices. This counterfeiting is so extensive and so dangerous in its effects that it would be most illogical to enact this bill, which is a serious attempt to safeguard the public health, without providing against this very real threat to it. It is wholly possible if not probable that certain features of this bill will be apt to increase counterfeiting, since they place a very high responsibility upon the legitimate manufacturer and if the irresponsible counterfeiter cannot be placed in fear of effective interstate commerce laws the general purposes of the proposed legislation will be seriously impaired by the expansion of the counterfeiter's activity. The same considerations which make the need for a Federal law covering impure food and drugs obviously apply to the need for a law which is comprehensive enough to cover counterfeiting.

The bill as now proposed has certain provisions in it which would affect this trade in counterfeit articles but a number of fairly simple amendments would have to be made in the law to make it fully effective for this purpose. We have prepared a schedule of amendments we deem necessary and will submit it to this committee. We submit this schedule separately, however, for it may be that the committee would prefer to include these provisions in a separate bill rather than in the bill under discussion. But we do urge most strongly that this committee deal with the evil of counterfeiting drugs either by modifying this bill to cover the situation or by recommending the passage of Senator Copeland's other bill (S. 783) introduced in the last session of Congress which expressly covers counterfeiting.

I will now proceed to discuss the specific provisions of the bill, which we believe requires some alteration, in order to make the law effective and at the same time unburdensome to perfectly fair business methods.

In making specific recommendations I will confine myself to subjects familiar to E. R. Squibb & Sons. I will not, therefore, attempt any comment upon the food provisions of the bill except as they are a part of sections dealing with drugs.

Definition of "adulterated." Page 5, section 4 (definition of the term "adulterated"):

> SEC. 4. A drug shall be deemed to be adulterated—
> (a) If it is or may be dangerous to health under the conditions of use prescribed in the labeling thereof—

should be amended to read:

> SEC. 4. A drug shall be deemed to be adulterated—
> (a) If it is generally dangerous to health under normal or customary usages or when used in the manner prescribed in the labeling thereof.

The inclusion of the words "or may be" before the word "dangerous" has the effect of designating a drug as adulterated even though the conditions of its use as prescribed in the labeling would be perfectly safe for all but a bare few persons who might possess particular idiosyncrasies for that drug. A person might develop abnormal reactions following the administration, for example, of neoarsphenamine or certain antitoxins. It would be most difficult, if not wholly impossible, to prescribe safe conditions of use for all persons. Even the elimination of these words "or may be" may not exclude the possibility of a manufacturer being held liable in cases of general sensitiveness, but their elimination removes an unfortunate emphasis from the language of the provision which if allowed to remain might make it impossible for a court to do otherwise than hold the manufacturer liable in a case where an injury arose solely by reason of a pronounced idiosyncrasy. It would be quite sufficient for the purposes of the bill, we believe, to limit the reference to a drug which is generally dangerous to health in normal or customary usages or under the conditions of use prescribed in the labeling. To overcome this objection we have utilized to some extent the language employed in the cosmetic section (p. 6, sec. 5 of S. 1994) in suggesting an alteration in the language used here. It is barely possible that this language may not cover all preparations which proponents of the bill seek to cover but it is submitted that it will include all drugs which reasonably can be included without imposing undue burdens on manufacturers and distributors.

Page 5, section 4 (b), also deals with definition of "adulterated" and grants the Secretary the right to prescribe tests and methods of assay under certain conditions. The paragraph reads in part as follows:

> (b) If its name is the same as or simulates a name recognized in the United States Pharmacopœia or National Formulary or in any supplement thereto, official at the time the drug is introduced into the interstate commerce, or if it purports to be such a drug, and it fails to meet the definition, formula, and description set forth therein, or differs from the standard of strength, quality, or purity as determined by the tests or methods of assay set forth therein; *except that whenever tests or methods of assay have not been prescribed therein or such tests or methods of assay as are prescribed are found by the Secretary to be insufficient, he is hereby authorized to prescribe by regulations, tests.* (Italics ours.)

And so forth.

This we believe should be amended by inserting after the word "insufficient" in line 16 the words "after notice and full public hearing." Also insert before the word "tests" in line 17 the words "which shall become effective 60 days after their promulgation by the Secretary." As so amended the pertinent portion would read:

> except that whenever tests or methods of assay have not been prescribed therein or such tests or methods of assay as are prescribed are found by the Secretary to be insufficient after notice and hearing, he is hereby authorized to prescribe by regulations, which shall become effective 60 days after promulgation by the Secretary, tests,

And so forth.

The Secretary of Agriculture as the proposed bill reads at present would have aribitrary powers to change or introduce without notice tests or methods of assay. The present U.S.P. and N.F. tests are known and followed throughout the industry. Alterations in the tests or the introduction of new tests involves considerable expense to the manufacturers and may result in far-reaching consequences. The right to alter or introduce such tests we believe should only be exercised after opportunity to hear and consider all sides of the question. The change should go into effect not less than 60 days after its promulgation by the Secretary. The proposed amendment to the bill should operate to lessen the chance of arbitrary or ill-considered changes or innovations being made.

Further in the paragraph occurs the following language (sec. 4 (b), line 18):

No drug shall be deemed to be adulterated under this paragraph if its label bears, in the manner and form prescribed by regulations of the Secretary, a statement indicating wherein its strength, quality, and purity differ, etc.

This we believe should be amended to read as follows (sec. 4 (b)):

No drug shall be deemed to be adulterated under this paragraph if its label bears immediately following the principal name of the preparation a plain and conspicuous statement indicating wherein its strength, quality, and purity differ from the standard of strength, quality, and purity set forth in the United States Pharmacopœia or National Formulary or in any supplement thereto, official at the time the drug is introduced into interstate commerce, as determined by the tests or methods of assay applicable under this paragraph nor, in the case of any variation from the official definition, formula, and description as set forth in said United States Pharmacopœia or National Formulary or supplement thereof, shall any drug be deemed to be adulterated under this paragraph if its label bears a plain and conspicuous statement indicating wherein the preparation fails to meet said definition, formula, and description, provided such variation from such official definition, formula, and description has not either materially affected the efficacy of such preparation or substantilly altered its identity.

E. R. Squibb & Sons are heartily in favor of any legislation which will clearly designate wherein a product bearing the U.S.P. or N.F. name differs from the U.S.P. or N.F. standard. The first part of this amendment is designed to eliminate the provision providing for regulations by the Secretary of Agriculture where the label bears in a conspicuous manner a statement wherein the product differs in strength, quality, and purity from U.S.P. or N.F. There is no need for separate regulations on this point. We believe it is preferable to have the requirement plainly stated in the law where it is perfectly possible to do so than to have the matter covered by regulation.

The second part is designed to cover a very definite need which even now exists under the present law. There are many articles which are defined in the U.S.P. or N.F. which because of their high viscosity or unstable form require the introduction of some nonactive ingredient to improve their availability for consumption. To introduce such an ingredient, however, is sometimes deemed to alter the indentity of the product and thus preclude the use of the U.S.P. or N F designation in referring to that product A very good example is the case of castor oil Castor oil is defined in the United States Pharmacopœia substantially as extract from the castor bean. Everyone knows that the high viscosity of pure castor oil makes it unpalatable and disagreeable to take. The introduction of certain oils render castor oil much more agreeable to the taste and thus promote its use. The amount of oil which is added is inconsequential so far as the efficacy of the product is concerned. Again, elements are introduced into products to keep them from freezing or dissolving under certain temperatures so that they may be constantly available for consumption. Their introduction does not affect the real identity or efficacy of the product but on the contrary most definitely improves it. It is no answer to say that the manufacturer may designate his product by a name other than the official name for the official name is the one the public are used to and readily recognize. The expenditure of large sums of money in advertising the product under the new name would be necessary to familiarize the product to the public even in the most general way. We realize the danger of possible abuse in permitting any variation from the identity of a product as fixed by the U.S.P. of N.F. but the provision which we have suggested which would require that the variation did not materially affect the efficacy or substantially alter the identity of the product would, we believe, check abuse in this respect. We urge the provision if only for the reason that it will permit and encourage the introduction and use of definite pharmaceutical improvements in existing U.S.P. and N.F. products.

Page 6, line 11, insert a new paragraph reading as follows:

Provided, however, no drug shall be deemed to be adulterated under this section if it is a drug liable to deterioration unless it can be shown that when such drug was introduced into interstate commerce either (1) it did not conform to the standard which it purported or was represented to possess or (2) it was not packaged or labeled in accordance with the provisions of section 8 (g) hereof.

It has long been felt by manufacturers of ethical medical preparations that it has been eminently unfair to place the stigma of adulteration upon the products of reputable manufacturers merely because drugs produced by them which unavoidably are liable to deterioration are subsequently found, sometimes years after their sale, to be below their original standard. The manufacturers have no objection to the designation of such drugs as deteriorated but when through absolutely no fault of their own these drugs fall below standard strength they should not be designated as adulterated, which designation carries with it at least to the public, implications of deliberate or careless acts. Provision may be made for stopping products in interstate commerce which have become deteriorated without designating them as adulterated and this should satisfy both the purposes of the Food and Drug Administration and the very reasonable sensibilities of the manufacturer. We have suggested such a provision under section 16 and have made corresponding suggestions where required.

Adulterated cosmetics, page 6, section 5, paragraph (a):

SEC. 5. A cosmetic shall be deemed to be adulterated (a) if it is or may be injurious to the user under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

We suggest that the words "or may be injurious to" be omitted so that the product would be deemed adulterated if it is likely to injure the normal user. As so amended, the provisions would read:

SEC. 5. A cosmetic shall be deemed to be adulterated:
(a) If it is generally injurious to the user under the conditions of use prescribed on the label thereof or under such conditions of use as are customary or usual.

The same reasoning which prompted the suggestion regarding a similar change in the definition of adulterated drugs prevails here. (See page 9.) It may be possible to vary the definition here by providing that the introduction of any deleterious substance whatever will constitute an adulteration. This language could not be employed in the case of drugs however as we have made the above suggestion largely for the sake of uniformity.

Misbranding, page 6, section 6, reads as follows:

SEC. 6. A food, drug, or cosmetic shall be deemed to be misbranded:
(a) If its labeling is in any particular false, or by ambiguity or inference creates a misleading impressions regarding any food, drug, or cosmetic.

Here we suggest that undue emphasis is placed upon the falsity in any particular of the label. Such language would make it difficult, if not impossible, for a court to avoid holding a manufacturer liable

for misbranding when his labeling contained a false statement in respect of an utterly immaterial and inconsequential fact. This emphasis is particularly unnecessary in view of the language which follows for, if by ambiguity or inference a misleading impression regarding the article is created or if the labeling is false, what article which is sought to be caught can escape the net? We are aware that considerable objection has been raised to the terms "ambiguity or inference" and "misleading impression" which occur in the definition quoted.

We find that this language or approximately this language has had the dignity of judicial usage (*U.S.* v. *95 Barrels of Vinegar*, 265 U.S. 438, p. 443), and we believe that reliance can be placed upon judicial interpretation to the extent that these phrases would not be applied in a burdensome and destructive manner. Some such phrases are needed, we believe, to correct existing abuses in labeling. Furthermore, the definition as written seems to approximate, at least, the existing law and there would appear to be no reasonable objection to having this law stated in statute form rather than in decisions to which the manufacturer has no ready access. We recommend that this provision should be amended so as to read as follows:

SEC. 6. A food, drug, or cosmetic shall be deemed to be misbranded:
(a) If its labeling is false in any material respect or by ambiguity or inference creates a misleading impression regarding such food, drug, or cosmetic.

Page 7, section 6 (b), line 1. We are uncertain as to the exact meaning of the term "in package form." This phrase is not defined except to include wrapped meats and the question is raised whether it should not be made perfectly clear that not only packages as the public generally understands that term but glass and metal containers as well are included.

We are aware that the term "package" has received liberal interpretation under the present law by the courts as well as in interstate commerce cases generally but for the purpose of making the section entirely clear we suggest an amendment to the definition on page 3, section 2, paragraph (k), so that it will read as follows:

(k) The term "in package form" includes articles packed in glass, metal, or other container material, as well as wrapped meats enclosed in paper or other materials as prepared by the manufacturers thereof for sale.

If the term "package" did not clearly cover a bottle the purpose of the provision would be to a very large extent destroyed.

Page 7, section 6 (b), line 5. Since the law itself provides that an accurate statement of the quantity of the contents in terms of weight, measure, and numerical count shall be included on the label, there scarcely seems to be any reason for further regulation on this subject by the Secretary and we would suggest therefore the elimination of the words in line 5 "as may be prescribed by regulations of the Secretary."

Page 7, section 6, paragraph (b), lines 8 and 9. The provision dealing with possible exemptions in the case of small packages now reads commencing at line 6, as follows:

* * * *Provided*, That under subdivision (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages of foods and cosmetics shall be established, by regulations prescribed by the Secretary.

This should be amended to exclude the words in lines 8 and 9 "of foods and cosmetics."

In this provision the Secretary is given the right to provide for exemptions as to small packages of foods and cosmetics. There is no good reason why the Secretary should not be allowed to prescribe variations and exemptions for drug packages as well as for food and cosmetic packages. For example, for hospitals and physicians' use certain tablets are placed in very small containers, so small that the name of the manufacturer, his place of business and a statement of the quantity of the contents in terms of weight, measure, or numerical count could not be included on the container in any legible form. It is therefore suggested that this proviso be amended so as not entirely to exclude the possibility of variations and exemptions respecting drugs.

Page 7, line 10. This provision whereby the Secretary may provide by regulation for exemptions covering the shipment of canned foods which are labeled at places other than where the products are processed or packed should also be extended to drugs and cosmetics as the same situation may and does obtain in the case of drugs. This amendment can be effected by striking out the words "canned foods" in line 11 and inserting in their place the words "foods, drugs, or cosmetics" as well as by eliminating the words "after notice and hearing" so that the proviso clause will read:

And provided further, That such classes of food, drugs, or cosmetics as the Secretary finds are, in accordance with the practice of the trade, labeled in substantial quantities at establishments other than the establishments where processed or packed, shall, etc.

Page 9, section 8. This section reads as follows:

SEC. 8. A drug shall be deemed to be misbranded:
(a) (1) If its labeling bears the name of any disease for which the drug is not a specific cure but is a palliative, and fails to bear in juxtaposition with such name and in letters of the same size and prominence a statement that the drug is not a cure for such disease; or (2) if its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.

In the first place, this paragraph uses, perhaps inadvertently, the words "specific cure" in one case and the word "cure" in another. This may well result in confusion. There are but comparatively few specific cures known to medicine—probably not more than 12 to 18 absolute specifics for the cure of disease—so that the provisions of this section would require practically every drug package to state that the drug is not a specific cure. There are, however, many drugs and preparations which have a specific action in the substitution or symptomatic treatment of disease and their use rather than being discouraged should be encouraged, as by it a definite and important relief can be effected. To mention but one such instance the case of insulin in the treatment of diabetes can be given.

The use of the term "contrary to the general agreement of medical opinion" which appears in section 8 (a) (2) is, we believe, unwise both from the point of view of the enforcing officer and the manufacturer. One need not dwell on the difficulty of finding general agreement of medical opinion on almost any subject. It is perhaps almost as intangible a substance as the general agreement of legal opinion. We would suggest that the general purposes of the provision would be just as effectively carried out by substituting for the words "contrary to the general agreement of medical opinion" the words "not supported by substantial medical opinion." As so

amended we believe that the provision would be much more practical in its administration and would actually reduce the burdens of the prosecuting officer in establishing his case. Our recommendation would, therefore, be that paragraph (a) should read as follows:

(a) (1) If its labeling bears the name of any disease for which the drug is not a cure or does not constitute specific substitution therapy and fails to bear in juxtaposition with such name and in letters of the same size and prominence as the name of the disease, a statement that the drug is not a cure for such disease; or (2) if its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is not supported by substantial medical opinion.

Page 11, section 8, paragraph (e), line 4: This subparagraph deals with preparations which do not have a name the same or similar to a name recognized in U.S.P. or N.F. and it requires that not only the common name of the drug be given but that the name and quantity or proportion of each active ingredient be borne on the label. The paragraph reads in part as follows:

(e) If it is not subject to the provisions of paragraph (b) of section 4 and its label fails to bear (1) the common name of the drug, if any there be, and (2) the name and quantity or proportion of each medicinal or physiologically active ingredient thereof.

We believe all reputable manufacturers would properly object to disclosure of their formulae which in substance this provision requires and it is respectfully submitted that it is severe and contrary to public policy to compel them to do so. Valuable property rights have been created in special formulae which competitors would be very quick to appropriate of they were aware of the exact quantities and proportions used. It is therefore natural and proper that the manufacturer would wish to guard from public knowledge the formulae under which his preparations are made. Even though this section requires only the disclosure of the active ingredients the objections are not overcome.

As written the provision would facilitate counterfeiting. Imitation products and all forms of "grafting" on the products of others might result from the disclosure of formulae respecting active ingredients and their proportions of an article which has required substantial expenditure and research to perfect. In every case it would result in the destruction of what has heretofore always been respected as a property right and in some cases it might operate even to destroy a well established and entirely legitimate business. It should be sufficient from the point of view of the public interest that merely the name of each active ingredient be furnished. The provision which is included in this paragraph allowing the Secretary to establish requirements for further information is far too broad and places entirely too great power in the hands of an individual. It should be eliminated as other provisions of the bill afford protection to the public from adulterated or misbranded goods. We therefore recommend that this section read as follows:

(e) If it is not subject to the provisions of paragraph (b) of section 4 and its label fails to bear the common name of the drug, if any there be, and the name of each medicinally or physiologically active ingredient thereof.

Page 11, section 8 (f), line 13:

(f) If its name is the same as, or simulates, a name recognized in the United States Pharmacopœia or National Formulary or any supplement thereto official at the time such drug is introduced into interstate commerce, and it is not packaged

or labeled as prescribed therein: *Provided, however*, that the Secretary may after notice and hearing grant exemptions from the requirements of this section where it is found that drugs are manufactured or processed in substantial quantities in establishments other than establishments where they are packaged or labeled if such drugs are packaged and labeled as prescribed by the United States Pharmacopœia or National Formulary or any supplement thereto prior to their removal from such packing or labeling establishment.

Frequently, a manufacturer has occasion to purchase drugs in bulk at places remote from his place of manufacture or packaging. The United States Pharmacopœia or National Formulary requirements are many times inapplicable in such a situation and provision should be made for the Secretary to permit exemptions in such cases. For example, the United States Pharmacopœia frequently requires that certain drugs be packaged in small colored bottles. If the Secretary should not be in a position to grant an exemption, it would be necessayr for a manufacturer who purchased his raw material elsewhere to buy all such material in a small packaged form. This would result in uneconomical practices and reasonable provision should be made to permit of variations from the usual rule. There seems to be no necessity of notice and hearing in granting such exemptions.

Page 12, section 8 (i). This paragraph dealing with disinfectants and antiseptics we believe should be entirely rewritten and we suggest the following in place of the present provision:

(i) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for any use on or within the human or animal body and its labeling fails to bear a statement clearly indicating its phenol coefficiency and the dilutions in relation to time of exposure in which it kills recognized test microorganisms; provided that any preparation may be labeled as an antiseptic if its directions for use provide for continuous contact with the part treated and in the strength used and in such contact and strength it is capable of preventing the growth of recognized test microorganisms with which it comes in contact. The Secretary may establish after notice and hearing bacteriological tests, including the various types of test microorganisms, to be used in determining phenol coefficiency, the strength of killing dilution in relation to time and growth inhibition.

The subject covered by this paragraph is somewhat technical and the proper wording of the paragraph demands considerable thought and careful expression. We have no pride of authorship in the proposal which we substitute but it should be pointed out that the paragraph in the bill as it is now written is not adequate in our judgment for two reasons. In the first place, up to the present time bacteriology has not developed tests which will measure the value of a preparation in terms of the extent to which micro-organisms are killed. It is well known that many antiseptics do not kill all micro-organisms but they do prevent their spread or check their growth and as such are quite properly designated as antiseptics. For a manufacturer not to be able to designate such preparations as antiseptics would be most unfair as well as unwise since their use has a beneficent effect. Even in medical usage such preparations are known as antiseptics. It is respectfully submitted that the paragraph as written improperly excludes a very important class or preparations from designation as antiseptics or disinfectants and would impair the use of effective products in attempting too narrowly to limit the use of those terms. Under our suggestion, as reputable tests are developed the Secretary of Agriculture may establish them for general standards. We believe that the suggestion put forward is reasonable in its application and makes provision for the possibility of scientific advances. Whether it is capable

of effective administration we are not so certain although in this respect we believe it is better than the provision for which it is substituted. Since the matter is technical and difficult to phrase,we would suggest as an alternative that the entire section be eliminated and that the matter be left to the provisions of section 4 (c) on page 6 of the bill which provide that a drug should be deemed to be adulterated:

If it is not subject to the provisions of paragraph (b) of this section (i.e., U.S.P. or N.F. preparations) and its identity or strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

False advertisement, page 12, section 9 (a), line 21:

This section reads as follows:

SEC. 9 (a). An advertisement of a food, drug, or cosmetic shall be deemed to be false if in any particular it is untrue or by ambiguity or inference creates a misleading impression regarding such food, drug, or cosmetic.

This provision is much more stringent than is desirable. If the advertisement is false or untrue in any particular the manufacturer would be criminally liable to prosecution. Under the present wording of the provision a mistake in the name of the manufacturer or in his address or in any unimportant or irrelevant particular included in the advertisement might be criminally actionable. We suggest the elimination of the words "in any particular" therefore as unnecessarily emphatic.

Page 12, section 9 (b). We recommend that this paragraph dealing with restrictions on the use of the name of a disease in connection with any advertising, be amended to read as follows for the same reasons that were set forth in connection with our proposed amendment of section 8 (a) dealing with labeling:

(b) An advertisement of a drug shall also be deemed to be false if it includes (1) the name of any disease for which the drug is not a cure or does not constitute specific substitution therapy and fails to state with equal prominence and in immediate connection with such name that the drug is not a cure for such disease; or (2) any representation, directly or by ambiguity or inference, concerning the effect of such drug which is not supported by substantial medical opinion.

Page 13, section 9 (c), lines 24 and 25, dealing with exemption in the case of dissemination to medical profession, etc.:

The word "pharmacological" is probably a typographical error for "pharmaceutical", but at any rate the words "dental" and "veterinary" should be included.

As amended these lines would read as follows:

If it is disseminated to members of the medical, dental, veterinary, and pharmaceutical professions only or appears in scientific preiodicals.

Permit factories, page 16, section 12. This provision enables the Secretary to issue permits under certain limited conditions to manufacture classes of food, drugs, and cosmetics. We believe that this provision, far-reaching as it may be in its consequences, does enable the proper officials to strike at practices which are injurious to health but which cannot now be adequately determined until after the articles in question have entered into interstate commerce. As it is written the Secretary is given the power to introduce a permit system practically upon his own responsibility. His power of acting is limited only in that he must show that by reason of the conditions surrounding the manufacture, processing, or packing of the articles that it is injurious to health and that the injurious nature cannot be adequately

determined until after the articles have entered into interstate commerce. If the provision elsewhere in the bill is not deleted that all findings of fact by the Secretary shall be deemed to be conclusive (see sec. 23 (h), p. 31) there is great room for arbitrary action. We would suggest, however, that the Secretary should not take this action without a full hearing after having given notice to all manufacturers who would be affected. We would therefore suggest the insertion of the words "after notice and hearing" after the word "Secretary" in line 6.

Since this section provides for the granting of a permit to factories to manufacture under certain conditions, there is danger that the manufacturer who has been granted such a permit will advertise to the trade that he holds a United States Government permit and thus treat what is really a badge of dishonor as a badge of Government approval. To cover this possibility we suggest the addition of the following at line 21, to be inserted just after the word "thereof":

Provided, however, That no manufacturer, processor, or packer to whom such a permit has been issued or renewed may in any manner in connection with the dissemination of this products or otherwise advertise the fact that such a permit has been so issued or renewed.

Factory Inspection. Page 17, section 13 (a), line 11.

It is our belief that the Government should be very reluctant to enter upon the broad field of factory inspection except in the specific cases covered by section 12. Section 13 would in effect give agents or employees of the Secretary the right to enter into any factory and inspect all equipment, methods, processes, materials, containers, and labels on pain of restraint of their goods in interstate commerce. Most of the manufacturers of drugs, as well as of foods, have many secret processes which they would be perfectly willing to disclose to the Government if they got no further. Everyone is aware, however, how frequently Government inspectors find their way into commercial establishments and it is no exaggeration to say that eventually what is in the hands of the Government is in the hands of the competitor. Furthermore, factory inspection is wholly unnecessary, once given the powers contained in section 12, to the true regulation of interstate commerce. With the broad powers already given the Secretary to check and seize goods in interstate commerce by injunction and libel, we believe that it is quite superfluous to include the inspection provisions contained in section 13. We therefore urge the deletion of the entire section.

Seizure. Page 20, section 16 (a), line 14.

This section reads in part as follows:

SEC. 16. (a) Any article of food, drug, or cosmetic in interstate commerce that is adulterated or misbranded * * * shall be liable.

After the word "misbranded" we suggest the insertion of the following:

or in case of drugs packaged and labeled in conformity with the requirements of section 8 (f) and (g) seizure which would be deemed to be adulterated under the provisions of the act were it not for the fact that such article became deteriorated after introduction into interstate commerce

This provision is inserted in order to provide for seizure of deteriorated articles which cannot under the provisions of the amendment

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suggested by us under section 4 (page 6, line 11) be libeled as adulterated.

Page 20, section 16 (a) (2), line 24.

Subdivision 2 of this section would give a chief of station or other officer of the food or drug administration the summary power of seizing without any court action any articles which he believed to be adulterated. We believe that the Federal courts of the country can be relied upon to act promptly enough for all practical purposes to check the dissemination in interstate commerce of adulterated goods upon proper cause shown by any officer of the Government and there seems to be no persuasive reason why such summary power should be given to an admistrative official. Some articles of food, drugs, or cosmetics which should be seized might get by as a result of the elimination of this paragraph but considerably more damage might well be done by the uncontrolled issuance of seizure orders by individuals.

Page 21, section 16 (c), line 22.

This section reads as follows:

(c) The court may, by order at any time before trial, allow any party to a condemnation proceeding to obtain a representative sample of the article seized.

It would seem that the party should be able to obtain such a sample as a matter of right and provision should be made that such a party can obtain a representative sample of the article seized upon request. The following amendment is therefore suggested:

(c) The court shall, by order at any time before trial, allow any party to a condemnation proceeding to obtain a representative sampel of the article seized.

Penalties. Page 23, section 17 (a) (1).

This section in parts reads as follows:

SEC. 17. (a) The following acts are hereby prohibited:
(1) The introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded.

Insert after the word "misbranded" the words:

or which would be deemed to be adulterated under the provisions of this act were it not for the fact that such food, drug, or cosmetic became deteriorated after its introduction into interstate commerce.

Line 12: After the word "misbranded" insert the same language as above.

The amendments are made in order to make possible full penalties for the dissemination in interstate commerce of articles which have become deteriorated after their earlier introduction in interstate commerce.

Page 25, section 17 (f), line 17. After the word "thereunder" insert the following:

or advertises the existence of a permit in violation of the provisions of section 12 (b).

This amendment is made in order to cover the amendment we suggested in section 12 (b), line 21, to insure that no improper or misleading use may be made by a manufacturer of the permit issued pursuant to that section.

Liability of corporate officers. Page 26, section 18 (b).

This reads as follows:

(b) Whenever a corporation or association violates any of the provisions of this act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation.

This section, we believe, has too broad an application and is a severe and unjust provision which will only engender opposition to the law as a whole. It places upon individual directors, officers, or agents of the corporation who may have acted absolutely innocently in the matter but who have given general authority to subordinates for acts which it ultimately developed have constituted in whole or in part a violation of the law. The entire section should be deleted or else some limiting language should be asserted. We suggest the addition of the word "knowingly" before the word "authorized." The situation which is sought to be covered by this provision, we believe, is one where the active participants in the misbranding or adulteration of a product seek to avoid any criminal liability by making use of the device of a corporation. It is not intended to impose liability on all officers or directors of a substantial manufacturing concern irrespective of whether they had any actual knowledge of the violation.

Injunction proceedings. Section 19 (a), line 13.

After the word "misbranded" insert:

or which would be deemed to be adulterated under the provisions of this act were it not for the fact that such food, drug, or cosmetic became deteriorated after its introduction into interstate commerce.

This amendment is also made to cover the case of articles which have become deteriorated after their introduction into interstate commerce.

Voluntary inspection service. Page 29, section 22.

We are entirely opposed to this section largely by reason of the fact that through difficulty of continued enforcement and through variation in terms of shapes and types of machinery and factories little, if any, real reliance could be placed on spasmodic Government inspection. Furthermore, when one factory requested this inspection service the next one would feel compelled to do it, and the whole thing would result in increased cost of operation for the entire industry. It would also require extensive personnel if the inspection were at all thorough, all of which would have a tendency to increase the burden of the Federal pay rolls without any real advantage to the public. The Government should hesitate, in our judgment, to extend its mark of approval on commercial goods in any form. We strongly urge the elimination of the entire section.

General regulations. Page 30, section 23.

We believe that one of the serious objections to the bill in its present form is the very wide power given to the Secretary of Agriculture to establish regulations. Section 23 gives him the general power to establish regulations and throughout the entire bill it is hard to find a section in which he is not given specific power to adopt regulations of some sort in regard to the subject matter of the section. To a large extent this is, perhaps, unavoidable but the power should be strictly limited, for we believe as the power is now granted it would to a large extent enable the Secretary of Agriculture to write a substantially new law. The proposed bill is not in the nature of emergency legislation and none of the arguments which may, perhaps with greater reason, be brought forward in the case of such legislation to favor the delegation of congressional powers can be properly adduced here. The power of the Secretary of Agriculture to establish regulations

should be limited to the specific provisions contained in the separate sections where the promulgation of such regulations is necessary within certain limits to carry out the purposes of the sections and the general authority should be amended to read:

The Secretary of Agriculture is authorized to prescribe such regulations as are necessary to administer the provisions of this act in an efficient manner, including regulations as to notice and conduct of hearings, but nothing herein contained shall authorize the Secretary to add to or diminish the substantive effect of the provisions of the act itself.

We also call attention to the fact that by paragraph (b) an attempt has been made to transfer bodily to the Secretary of Agriculture the very broad powers of the Federal Trade Commission to gain access, investigate, and issue subpoenas which are the subject of sections 9 and 10 of the Federal Trade Commission Act It is one thing to grant such powers to a commission and another thing to grant the power to the Secretary of Agriculture or any other single officer of the Government. An examination of the sections of the Federal Trade Commission Act discloses that they go far beyond any reasonable needs to control the labeling and advertising of food, drug, and cosmetic products and it is submitted that the attempt to transfer them from an entirely different act framed for a different purpose to this act by general reference is not the way to deal with the specific problems covered by this proposed bill. One of the chief purposes of the Federal Trade Commission Act was to grant the Federal Trade Commission the power to gather and compile complete information respecting corporations engaged in interstate commerce and the provisions of sections 9 and 10 were apparently designed to assist the Commission to gather such information. As applied to the administration of the food, drug, and cosmetic legislation it would seem almost inevitable that such powers would result in irksome and annoying requests for irrelevant information unrelated to specific abuses. Other provisions of the proposed bill give the Secretary of Agriculture broad powers which should be wholly adequate for effective enforcement of the act without making available to him rights which have been heretofore given only to a commission. We strongly urge the deletion of this subparagraph.

We would also eliminate the last sentence of paragraph (c) on page 31, reading:

* * * The findings of fact by the Secretary shall be conclusive if in accordance with law.

We do not understand why findings of fact by the Secretary shall be treated as conclusive. As the proposed bill is written the most vital issues in any condemnation or other proceedings under the act will be questions of fact. The Secretary as the bill is drawn is the initiator of all charges and if this language is continued he also becomes the final arbiter on the facts. There may be some justification for such a rule in the case of commissions which are constituted in a quasi-judicial form but we know of no precedent whereby an individual governmental officer is given such a vitally important power. We would think that the general unwisdom of this provision is so obvious that the committee will readily agree to its elimination. It is possible that this language is not intended to have any other application than to hearings which are authorized and required by the act, namely, for the purpose of formulating regulations and granting exemptions.

It is not clear that this is so, however, from the language and, in any event, we would be inclined to believe that this would be understood without specific provision.

Liability for personal injuries.

Page 31, section 24:

This section reads as follows:

SEC. 24. A right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this act.

Under the provisions of the common law, one proximately injured by the negligent or false representation of a manufacturer is liable for damages resulting therefrom and there is little hesitation on the part of the public to avail itself of the law as it now stands.

There is already prevalent to an astonishing extent among the consuming public the feeling that a real or fancied defect in a food, drug, or cosmetic is the starting point for the recovery of heavy damages from the manufacturer. Due to the serious effects of any actions at law based upon such defects brought against a manufacturer to that manufacturer's business, little, if any, encouragement is needed by a manufacturer to take all reasonable precautions that he can to protect his products. We urge that this section, therefore, be deleted as it will serve only as an embarrassment to honest manufacturers and will not substantially increase any rights which the public now has in this regard. It seems also to be inconsistent in its terms with the last sentence of section 15 (b) which provides that all suits brought under the act should be brought in the name of the United States.

This completes our suggestions as to the bill. There may be considerations which have not occurred to us which would cause us, perhaps, to modify or add to the suggestions we have made. They represent as presented, however, our best judgment at present on the form which the bill should take. We believe that the suggestions are worthy of consideration if only for the reason that they emanate from a manufacturer whose chief and constant policy over a long period of years has been to manufacture drugs and medicinal preparations of the highest possible quality. We reiterate that we are strongly in favor of the enactment of legislation accomplishing the general purposes of this bill and, where we have criticized certain provisions in it we have done so in the belief that changes are either essential or highly advisable if the bill is to be enacted into law. We believe that we have made concrete and constructive suggestions wherever we have taken it upon ourselves to criticize any provisions of the bill.

There are certain amendments which I desire to propose to the bill to cover counterfeiting of labels.

Page 3, section 2 (dealing with definitions of terms used in the bill), paragraph (h), now reads as follows:

SEC. 2. As used in this Act, unless the context otherwise indicates—

* * * * * * *

(h) The term "label" means the principal label or labels (1) upon the immediate container of any food, drug, or cosmetic, and (2) upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic.

For the purpose of making this paragraph cover the counterfeiting of labels we suggest that it be amended to read as follows:

(h) The term "label" means the principal label or labels, or any label, labels, printed matter or other device or devices used to designate the producer, manufacturer, packer, owner, or seller of any food, drug, or cosmetic (1) upon the imme-

diate container of any food, drug, or cosmetic, or (2) uopn the outside container or wrapper, if any there be, or any retail package of any food, drug, or cosmetic, and any label, labels, printed matter or other device or devices designed to be affixed by any means or in any manner whatsoever to any such container, wrapper or retail package for the purpose of designating the producer, manufacturer, packer, owner, or seller of the contents thereof.

There should be inserted between paragraphs (i) and (j) of section 2, page 3, the following additional paragraph to be numbered (j):

(j) The term "counterfeit label" means any label which is so made as to induce the belief that the food, drug, or cosmetic in connection with which it is used or intended to be used is the product or property of a person other than the actual producer, manufacturer, packer, owner, or seller thereof.

Page 17, section 13 (dealing with factory inspection), paragraph (a), provides as follows:

SEC. 13. (a) In order adequately to regulate interstate commerce in food, drugs, and cosmetics, and enforce the provisions of this Act, officers or employees duly designated by the Secretary, after first obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter any factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed, or held for shipment in interstate commerce or are held after such shipment, or to enter any vehicle being used to transport such food, drugs, or cosmetics, in interstate commerce; and (2) to inspect such factory, warehouse, establishment, or vehicle and all equipment, methods, processes, finished and unfinished materials, containers, and labels there used or stored.

We have already urged the omission of this paragraph. However, if the paragraph is for any reason not eliminated, we suggest that subdivision (1) thereof be amended to read as follows:

* * * (1) to enter any factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed, or labels are printed, or any of the foregoing are held for shipment in interstate commerce or are held after such shipment, or to enter any vehicle being used to transport such food, drugs, cosmetics, or labels in interstate commerce; * * *.

Paragraph (b) of said section 13 now reads as follows (page 18):

(b) (1) The several district courts of the United States are hereby vested with jurisdiction to restrain by injunction temporary or permanent, the shipment in interstate commerce or delivery after receipt in interstate commerce of any food, drug, or cosmetic from or by any factory, warehouse, establishment, or vehicle, if the owner, operator, or custodian thereof has denied to officers or employees duly designated by the Secretary permission so to enter and inspect such factory, warehouse, establishment, or vehicle and equipment, methods, processes, finished and unfinished materials, containers, and labels there used or stored. Whenever such permission is granted, the injunction issued pursuant to this paragraph shall be dissolved, or may be continued in force subject to such conditions governing the inspection as the court may order; and (2) violation of any such injunction may be summarily tried and punished by the court as a contempt. Such contempt proceedings may be instituted by order of the court or by the filing of an information by the United States attorney.

The first sentence of this paragraph should be amended by striking out the word "or" in front of the word "cosmetic" in line 5 and by adding after said word "cosmetic" the words "or label", so that such sentence shall read as follows:

(b) (1) The several district courts of the United States are hereby vested with jurisdiction to restrain by injunction temporary or permanent, the shipment in interstate commerce or delivery after receipt in interstate commerce of any food, drug, cosmetic, or label from or by any factory, warehouse, establishment, or vehicle, if the owner, operator, or custodian thereof has denied to officers or employees duly designated by the Secretary permission so to enter and inspect such factory, warehouse, establishment, or vehicle and equipment, methods, processes, finished and unfinished materials, containers, and labels there used or stored. * * *

Page 18, section 14, dealing with records of interstate shipment, now reads as follows:

SEC. 14. For the purpose of enforcing the provisions of this act, carriers subject to the Interstate Commerce Act, as amended (U.S.C., title 49), and other carriers engaged in interstate commerce, and persons receiving food, drugs, or cosmetics in interstate commerce, shall, upon the request of an officer or employee duly designated by the secretary, permit such officer or employee to have access to and to copy all records showing the movement in interstate commerce of any food, drug, or cosmetic, and the nature, kind, quantity, shipper, and consignee thereof, and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any record so requested: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.

This section should likewise be amended by striking out the word "or" in front of the words "cosmetic" in line 25 on page 18 and line 4 on page 19, and adding thereafter the words "or label", so that the section will read as follows:

SEC. 14. For the purpose of enforcing the provisions of this act, carriers subject to the Interstate Commerce Act, as amended (U.S.C., title 49), and other carriers engaged in interstate commerce, and persons receiving food, drugs, cosmetics, or labels in interstate commerce, shall, upon the request of an officer or employee duly designated by the secretary, permit such officer or employee to have access to and to copy all records showing the movement in interstate commerce of any food, drug, cosmetic, or label, and the nature, kind, quantity, shipper, and consignee thereof, and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any record so requested: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.

Page 19, section 15 (dealing with investigations and institution of proceedings), paragraph (*b*), now reads as follows:

(b) It shall be the duty of each United States attorney to whom the Secretary reports any violation for institution of criminal, libel for condemnation, or other proceedings under this act, or to whom any health, food, or drug officer of any State or Territory, or political subdivision thereof, presents evidence satisfactory to the United States attorney of any such violation, to cause appropriate proceedings to be instituted in the proper courts of the United States without delay. All suits instituted under this act shall be by and in the name of the United States.

Said paragraph (*b*) should be amended to authorize each United States attorney to commence an action not only upon the report of the Secretary and upon evidence presented by any health, food, or drug officer, but also upon the compalint of any individual, firm, or corporation. This will enable prosecutions against counterfeiters to be started upon the complaint of the one whose labels are being counterfeited. As so amended, the paragraph would read as follows:

It shall be the duty of each United States attorney, to whom the Secretary reports any violation for institution of criminal, libel for condemnation, or other proceedings under this act, or upon the presentation of satisfactory evidence by any health, food, or drug officer of any State or Territory or political subdivision thereof or, in any case involving any counterfeit label attached or unattached to any food, drug, or cosmetic, or any die, plate, brand, or other thing intended for use in making such a label, upon the complaint of any individual, firm, or corporation, to cause appropriate proceedings to be instituted in the proper courts of the United States without delay. All suits instituted under this act shall be by and in the name of the United States.

Page 20, section 16 (dealing with "seizure"), paragraph (*a*), reads as follows:

(*a*) Any article of food, drug, or cosmetic in interstate commerce that is adulterated or misbranded or that has been manufactured, processed, or packed in a

factory or establishment, the operator of which did not, at the time of manufacture, processing, or packing, hold a valid permit if so required by regulations under section 12, shall be liable to be proceeded against while in interstate commerce or at any time thereafter on libel of information and comdemned in any district court of the United States within the jurisdiction of which the article is found. The article shall be liable to seizure (1) by process pursuant to the libel, or (2) if a chief of station or other officer of the Food and Drug Administration, duly designated by the Secretary, has probable cause to believe that the article is so adulterated as to be imminently dangerous to health, then by order of such officer, issued under his oath of office, particularly describing the article to be seized, the place where located, and the officer or employee to make the seizure. In case of seizure pursuant to any such order, the jurisdiction of the court shall attach upon such seizure. Any article seized pursuant to any such order shall thereupon be promptly placed in the custody of the court and a libel of information shall be promptly filed for condemnation thereof.

We have already suggested that this paragraph be amended to read as follows:

(*a*) Any article of food, drug, or cosmetic in interstate commerce that is adulterated or misbranded, or, in the case of drugs packaged or labeled in conformity with the requirements of section 8 (*f*) and (*g*), that would be deemed to be adulterated under the provisions of this act, were it not for the fact that such article became deteriorated after introduction into interstate commerce, or that has been manufactured, processed or packed in a factory or establishment, the operator of which did not, at the time of manufacture, processing, or packing, hold a valid permit if so required by regulations under section 12, shall be liable to be proceeded against while in interstate commerce or at any time thereafter on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. The article shall be liable to seizure by process pursuant to the libel.

We further suggest that after the word "misbranded" in line 14 there be inserted the words "or to which a counterfeit label has been attached," and that after the figure 12 in line 19 there be inserted the words "or any counterfeit label".

As thus finally amended, said paragraph will read as follows:

(*a*) Any article of food, drug, or cosmetic in interstate commerce that is adulterated or misbranded, or to which a counterfeit label has been attached, or in the case of drugs packaged or labeled in conformity with the requirements of section 8 (*f*) and (*g*), that would be deemed to be adulterated under the provisions of this act were it not for the fact that such article became deteriorated after introduction into interstate commerce, or that has been manufactured, processed or packed in a factory or establishment, the operator of which did not, at the time of manufacture, processing, or packing, hold a valid permit, if so required by regulations under section 12, or any counterfeit label, shall be liable to be proceeded against while in interstate commerce or at any time thereafter on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. The article shall be liable to seizure by process pursuant to the libel.

Paragraph (*d*) of said section 16 now reads as follows (p. 21, line 1):

(*d*) Any article of food, drug, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article of food, drug, or cosmetic shall not be sold or disposed of contrary to the provisions of this act or the laws of any State or Territory, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the party obtaining release of the article under bond. Any article condemned by reason of the manufacturer, processer, or packer not holding

a valid permit when so required by regulations under section 12 shall be disposed of by destruction.

The first line of said paragraph should be amended by striking out the "or" in front of the work "cosmetic" and inserting after such word the words "or any label." The first clause of said paragraph would thus read as follows:

(*d*) Any article of food, drug, cosmetic, or any label, condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this act of the laws of the jurisdiction in which sold: * * *.

Page 23, section 17 (which deals with penalties), paragraph (*a*), subdivisions (1) and (2), now reads as follows:

SEC. 17. (*a*) The following acts are hereby prohibited:

(1) The introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded.

(2) The receipt in interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded and the delivery of proffered delivery thereof in the original unbroken package for pay or otherwise.

We have already suggested that said subdivisions be amended to read as follows:

(1) The introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded or which would be deemed to be adulterated under the provisions of this act were it not for the fact that such food, drug, or cosmetic became deteriorated after its introduction into interstate commerce.

(2) The receipt in interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded or which would be deemed to be adulterated under the provisions of this act were it not for the fact that such food, drug, or cosmetic became deteriorated after its introduction into interstate commerce, and the delivery or proffered delivery thereof in the original unbroken package for pay or otherwise.

We suggest that these subdivisions be further amended by inserting in each thereof after the word "misbranded" the words—

or to which a counterfeit label is attached,

and after the word "commerce" at the end of subdivision (1) and toward the end of subdivision (2), the words—

or of any counterfeit label, or die, plate, brand, or other article intended for use in the making of any such label.

As thus amended, said subdivisions (1) and (2) would read as follows:

(1) The introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded, or to which a counterfeit label is attached, or which would be deemed to be adulterated under the provisions of this act were it not for the fact that such food, drug, or cosmetic became deteriorated after its introduction into interstate commerce, or of any counterfeit label, or die, plate, brand, or other article intended for use in the making of any such label.

(2) The receipt in interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded, or to which a counterfeit label is attached, or which would be deemed to be adulterated under the provisions of this act were it not for the fact that such food, drug, or cosmetic became deteriorated after its introduction into interstate commerce, or of any counterfeit label, or die, plate, brand or other article intended for use in the making of any such label, and the delivery or proffered delivery thereof in the original unbroken package for pay or otherwise.

There should be inserted between subdivision (6) of said paragraph (*a*) and paragraph (*b*), of said section 17, page 24, the following additional subdivision:

(5) The making of any counterfeit label or the possession of any counterfeit label knowing it to be such, or of any die, plate, brand, engraving or other thing for the purpose of counterfeiting a label, or the affixing of any counterfeit label to any food, drug, or cosmetic or the sale or keeping or offering for sale or disposing of any food, drug, or cosmetic to which a counterfeit label is attached, within any territory.

Page 27, section 20 (dealing with imports), paragraph (*a*), now reads as follows:

SEC. 20 (*a*) The Secretary of the Treasury shall deliver to the Secretary of Agriculture upon his request, from time to time, samples of food, drugs, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) any false advertisement of such food, drug, or cosmetic has been disseminated in the United States within 3 months prior to the date such article is offered for import, or (2) such article has been manufactured, processed, or packed under unsanitary conditions, or (3) such article is adulterated or misbranded within the meaning of this act, then such article shall be refused admission.

The word "and" preceding the word "cosmetics" in line 11 should be deleted and after said word "cosmetics" there should be inserted the words "and labels". Also, subdivision (3) of said paragraph should be amended to read as follows:

(3) such article is adulterated, misbranded, or has a counterfeit label affixed thereto within the meaning of this act or when such label is counterfeit, then such article or label, as the case may be, shall be refused admission.

As thus amended, said paragraph (*a*) of section 20 would read as follows:

SEC. 20 (*a*) The Secretary of the Treasury shall deliver to the Secretary of Agriculture upon his request, from time to time, samples of food, drugs, cosmetics, and labels which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) any false advertisement of such food, drug, or cosmetic has been disseminated in the United States within 3 months prior to the date such article is offered for import, or (2) such article has been manufactured, processed, or packed under unsanitary conditions, or (3) such article is adulterated or misbranded within the meaning of this act, or (4) such article is a counterfeit label within the meaning of this act or has a counterfeit label affixed thereto, then such article shall be refused admission.

Senator COPELAND. Mr. William F. Heide and Dr. Stroud Jordan of the National Confectioners Association will share 10 minutes. Mr. Heide.

STATEMENT OF WILLIAM F. HEIDE, NATIONAL CONFECTIONERS ASSOCIATION

Mr. HEIDE. Mr. Chairman and members of the committee, I am associated with the firm of Henry Heide, Inc., founded in 1869, and have been active in the confectionery industry for over 38 years. I have the honor of representing the National Confectioners Association of the United States at this hearing, an organization that has been in existence for over 50 years. Its motto has been "Purity, Quality of Product."

The association represents about 80 percent of the wholesale manufactured confectionery of the United States. We have always encouraged the manufacture of wholesome pure candies, candies of quality.

Our association a great many years ago went on record offering a reward of $1,000 to the first case that was proven against our industry of an individual poisoned by confectionery, and up to the present time no claim has ever been substantiated to that reward.

Mr. Chairman, we are in sympathy with the Pure Food and Drugs Act, but the present proposed bill will inflict a great deal of hardship on our industry. There are a great many impractical suggestions in the bill which would make it almost impossible for us to conform to it. I am not going to go into detail myself as to what some of these specific hardships would be. I am accompanied by Dr. Jordan, chief chemist in our establishment for a period of over 10 years and who is still associated with us, in part time; and I brought Dr. Jordan down here with me and he will give you a few detailed graphic examples where this proposed bill is not possible of application in our industry.

I will now ask Dr. Jordan to address you.

Senator COPELAND. Thank you, Mr. Heide. Dr. Jordan, we will now hear you.

STATEMENT OF DR. STROUD JORDAN, NATIONAL CONFECTIONERS ASSOCIATION

Dr. JORDAN. Mr. Chairman and members of the committee, first let me go on record as being absolutely in favor of all of the objects sought in the proposed bill. I believe I convey the same impression from the confectionery manufacturers throughout the United States.

For more than 6 years I have been personally interested in the standardization of confectionery. At the present time there is a second volume off the press in May 1933 having to do with this very matter. In this volume there have been pointed out discrepancies which exist in present definitions and standards; those which fail to standardize and those which fail to define. Other definitions have been suggested for confections. I am stating this in order to show you the absolute honesty of purpose I have in speaking to you.

There are some things in the bill which are both impractical and impossible insofar as the confectionery industry is concerned. It will not be necessary, nor is it indicated for me to speak concerning the legality or the conveyance of absolute power to the Secretary, because that has been well covered.

I would like, first, to refer to the section having to do with the labeling and specifically that of misbranding. The essence of the statement is, any food product not covered by definitions or standards shall be considered to be misbranded if, first, it does not carry a common or ordinary name of the product, if there be any; and, secondly, if it does not carry a common or ordinary name of each of the materials used, except that spices, flavors, and colors may be designated as such. Well, this special provision, insofar as labeling is concerned, may be applicable to many industries. In the confectionery industry we are in a peculiar position. I would like, first of all, to show you a jar of hard candy that is sold at 20 cents or less per pound.

Senator COPELAND. You can leave that here.

Dr. JORDAN. I shall be glad to leave it with you, Senator. This particular jar of candy is a stock item and is sold in 30-pound pails and also in barrels. It is pushed out at Christmas by the retailers; and I believe all of you are familiar with the time when some of us used to steal our grandmother's stocking to hang up at Christmas because ours would not hold enough.

It is absolutely impossible to define this type of candy on a label. I am submitting here the statement on that particular jar. There are 26 separate and distinct shapes, 15 separate and distinct fillings, 10 flavors, assorted, and 10 solid colors. In the first place, the space would not permit; and, in the second place, if that were to be labeled, any change in that mixture would be a violation provided it did not carry everything that was set up in the order of predominance by weight.

I respectfully submit that when you make from 500 to 1,000 pounds of candy, each lot running from 25 to 50 pounds, and spread it out on a table, you will see that it is absolutely impossible to have a uniform mixture in each jar.

In addition to this, I might cite examples of general stock mixtures containing gum drops, jellies, hard candies, and so forth, 5 and 6 items that would have different flavors and compositions in each. I could also show you a 5-pound stock box of Christmas mix which contains a definite quantity of chocolates along with other materials, such as gum drops, and so forth. In this particular box of 5-pound Christmas mix, which is sold to the consumer through retail stores, it is sold in bulk. Therefore, any statement made on the package would serve no purpose, so far as the consumer is concerned.

Senator COPELAND. You have been addressing yourself particularly to subsection (f) on page 9?

Dr. JORDAN. Yes, sir.

Senator COPELAND. Now, have not standards been described for these candies?

Dr. JORDAN. If it may please you, I would like to refer to the fact that up to the present time the old food inspection decision 29, as signed by James Wilson in 1905, having to do with foods has had to do with confection. It has always been held that the type of product of this sort, since it does not represent anything of natural origin and, therefore, could not be taken to be an imitation of anything of natural origin, there was no need to state the presence of added color, flavor, or other materials, provided they are wholesome and no harm can come of their consumption.

Senator COPELAND. I observe that as written it says, "If it purports to be or is represented as a food for which no definition of identity has been prescribed by regulations."

Dr. JORDAN. There are no definitions for any candy.

Senator COPELAND. Would it not be a simple matter to formulate definitions that would be entirely acceptable to the trade?

Dr. JORDAN. I can answer that very briefly, Senator. Yes; but it is impossible to formulate definitions to cover new goods, because new goods are not new in formulas or formulated to cover them. Therefore, if an individual makes a new mixture and offers it to the trade, until such time as the Secretary shall elect to state such definitions, it must carry definitions.

Senator COPELAND. Would not that new article be likely to be only in the addition of spice, flavor, or color?

Dr. JORDAN. No; you have a combination of 15 different materials that might enter into the mixture. Any of the 5-cent candy bars that appear on the market at this time may be considered to be a mixture similar to this mixture, except they are under one chocolate jacket. Let us take a 5-cent bar; a fudge center, rolled into caramel, dropped into peanuts and covered with chocolate. You have four distinct materials. Which is it? If we take it as one material, no two bars would be exactly the same. There would be a predominance of peanuts in one case and chocolate in another.

Senator COPELAND. I take it, Doctor, that you will now or later present substitute language or definite suggestions about that?

Dr. JORDAN. Yes, sir; I have that with me.

As the matter of inspection has been covered very nicely in previous talks, I have only this to say insofar as inspection is concerned. If there are no secret processes or trade practices exposed, of which there are many in the confectionery industry, there may be those of you here who do not believe this—I can give you many illustrations—if there is an inspector who likes to remain in Government service for an indefinite period of time, then so far as his personal gain is concerned it will be negligible; but let us suppose I am inspecting the factory of Mr. A and later Mr. B, and I find Mr. B making some goods for Mr. A. Out of the goodness of my heart I see him doing a job which is done in a very crude manner, and I say to him, "why don't you do so and so?" It is not necessary for me to go further. You can realize what will happen.

Information can be passed on by word of mouth which will be of distinct harm to the manufacturer insofar as secret processes are concerned. I will not give you illustrations unless they are asked for.

The next and last statement I have to make is with reference to section 34, regarding the liability for personal injury. Section 24, I believe——

Senator COPELAND. I am not very keen about having that in the bill. I cannot for the life of me see why it should be in there.

Dr. JORDAN. I have had quite a lot of experience in running down things of this sort. I was called out hurriedly one day to look into an embargo on candy in one of the large cities of the United States. I found that the Health Department had embargoed it on the recommendation of a physician. The physician had claimed that two children had been poisoned from eating this candy. This particular piece of candy was candy of the Easter egg variety, which are naturally colored. I do not know what had been the trouble previously, but the children had not been able to retain it on their stomachs. It was indicated to the physician that perhaps there were lesions. Anyhow, he jumped to the conclusion that the children had been poisoned. The inspector asked the physician if he was sure of his diagnosis. The inspector asked to have a diagnostician sent for. The children were found to have diphtheria, one in an advanced stage and the other an inceptive stage.

Senator COPELAND. I did not know that doctors ever made mistakes like that.

Dr. JORDAN. They make as many mistakes as chemists.

Now, let us suppose that the physician had stuck to his diagnosis, and the inspector had not been familiar enough with matters to call in the diagnostician. There is no need to show what might have happened. Even though the manufacturer had gone scot free the unwarranted publicity would have ruined his business. Is it necessary to give unlimited power on publicity of products which may be adulterated rather than those which are definite? With that statement, I will be glad to leave the other sample.

STATEMENT OF ALFRED T. FALK, DIRECTOR OF RESEARCH AND EDUCATION OF THE ADVERTISING FEDERATION OF AMERICA, NEW YORK CITY

Mr. FALK. The Advertising Federation of America, which I represent, is a national organization consisting of about one hundred local advertising clubs in all parts of the country, 15 national advertising associations interested in special phases and branches of advertising, and about 400 individual companies which are sustaining members of the Federation and which include owners of advertising media, advertising agencies, and large national advertisers.

The Advertising Federation wholeheartedly approves the objectives of Senate bill 1944 as stated in its title. It is recognized that these objectives, if they are effectively attained, will bring not only greater protection for the public health but will also strengthen and increase the usefulness of advertising as a means for selling goods.

The Advertising Federation of America has for more than 20 years been an aggressive proponent of the "truth in advertising" movement and welcomes any constructive practical legislation which will help to increase the believability of advertising.

The degree of progress which has been made in advertising ethics during the past 30 or 40 years is amazing, despite the fact there still are some bad practices here and there. Not much more than a generation ago almost every advertisement could safely be assumed to be false or at least greatly exaggerated and many a business man refrained from advertising in order to safeguard his reputation. With the passage of years all this has been completely changed and advertising is now used as one of the best means of establishing a manufacturer's reputation for integrity and the quality of his goods. Much of the credit for this tremendous improvement is due to the organized efforts of advertising men in policing their own industry, largely through educational means.

Senate bill 1944 aims to correct some of the advertising abuses which still exist and we can but applaud its stated intent.

Speaking only of such portions of this bill as affect advertising, we see a number of flaws in drafting the individual provisions. These defects are so serious that we are inclined to question whether the bill in its present form does not contain greater possibilities for harm than for good. But rather than oppose the passage of a bill under this title, we submit that a number of modifications are necessary. Because of its wide general membership, including persons in all phases of business, the Advertising Federation is in a position to approach the matter from the angle of the consumer and small retailer, as well as that of the publisher and the national manufacturer.

Referring specifically to section 9 of the bill, covering false advertising, we find that the provisions are so vague and sweeping that hardly any advertiser may know positively whether his advertising is within the law. Besides being extremely indefinite, this section of the bill provides that an advertiser may be severely punished for honestly and frankly stating a complete truth, a situation which should never be possible in an intelligently drafted law.

I shall take up the individual paragraphs. Paragraph (*a*) contains the exceedingly vague language which makes an advertisement false if in any particular whatsoever it, by ambiguity or inference, creates a misleading impression. The objectionable nature of this language is so obvious that I hardly need to point out what is wrong with it. For the sake of brevity in this presentation I merely offer a substitute. I recommend that paragraph (*a*) of section 9 be revised to read as follows:

> An advertisement of a food, drug, or cosmetic shall be deemed to be false if in any material particular it is untrue or deceptive.

To my mind this seems to cover the matter entirely. However, any other language equally definite would be satisfactory.

In paragraph (b), clause (1) contains a provision which will require that the advertisements of many well-known and beneficial remedies must carry the words "not a cure" with equal prominence and in immediate connection with the name of the disease for which it is a palliative for. Though the drug itself be generally recommended by physicians everywhere for use in connection with such disease, the manufacturer of this remedy is by law required to frighten possible purchasers from buying it.

Clause (a) of paragraph (b) provides that an advertisement shall be deemed to be false if it includes any representation concerning the effect of a drug which is contrary to the general agreement of medical opinion. The volume of argument against the phrase "general agreement of medical opinion" has already grown to such proportions I need not add to it. To sum it all up, the phrase may be characterized as ridiculous. My suggestion for a substitute for clause (a) is as follows:

> Any representation concerning such drug which is not supported by scientific or medical test.

In paragraph (c) which is designed to protect the public against dangerous self-medication, it seems that the restriction on advertising is too severe. As it now reads, the paragraph prohibits any advertisement of a drug representing it to have any effect in the treatment of a list of diseases. It should be adequate if the word "curative" be inserted before the word "effect" which would permit the advertiser to mention the name of a disease, but would prohibit him from making any representation that the drug has a curative effect upon it.

There are many other defects in this bill as now written, but because I represent officially only the Advertising Federation of America, I have confined my specific criticism to the advertising section of the bill. Many of the criticisms which were voiced at this hearing pertain to features of the bill which would work great harm upon members of our organization in their individual businesses but these matters have already been so ably presented that in order to conserve time, I shall not refer to them specifically. In a general way, however, we wish

to enter a protest against the excessive use of the third person singular pronoun in connection with the enforcement provisions. It appears that we have seldom had the privilege of studying such an ambitious outline for granting autocratic power to an executive officer of the United States Government. This feature, I feel sure, need not be further criticized in this brief for it does not seem possible that a Senate committee would refer a bill to Congress without greatly changing it. There are many places in the bill where the language can just as well be made specific as to what Congress intends to prohibit rather than leaving the matter to the discretion of an official.

Our greatest immediate concern in the whole matter is the possible effect on economic recovery in this country. There is not the least doubt that the passage of this bill without modifications would so greatly discourage manufacturers and sellers of foods, drugs, and cosmetics from attempting to advertise their wares that the volume of their advertising would be reduced tremendously. This in turn could not help but radically shrink the volume of business in this field which would naturally result in substantial lessening of employment and profits.

We respectfully urge, Mr. Chairman, that your committee give favorable consideration to the specific points referred to above as well as the many excellent constructive suggestions which have been made by others during the course of this hearing.

Senator COPELAND. We will now hear Mr. L. B. Thompson, general counsel for the Proprietary Association.

STATEMENT OF H. B. THOMPSON, GENERAL COUNSEL FOR THE PROPRIETARY ASSOCIATION

Mr. THOMPSON. Mr. Chairman, my name is H. B. Thompson, and I am general counsel for the Proprietary Association. That association has among its membership those who manufacture the greatest portion of the so-called patent or proprietary medicines sold and distributed in the United States.

I was delighted yesterday, Mr. Chairman, when you disclaimed the authorship of this bill and lack of knowledge of its author. I have had experience with you, Mr. Chairman, and I have found you to be uniformly fair—when you were health officer of the city of New York, having due regard not only for the public service but for people who might be engaged in industry.

Senator COPELAND. I want the record to show that I have not given a retainer to Mr. Thompson.

Mr. THOMPSON. No; I am the only one that has a retainer in this particular matter.

Let me say at the outset that I heartily concur in the statement of Professor Beale, who suggested that, in his opinion, the only manner in which the present bill could be properly amended was to strike out all after the enacting clause.

I have been for a good many years interested in legislative matters. I have been seeking, if possible, to find the pathogenesis—or etiology, perhaps I had better say—in this bill. I have examined the authorities. I read some of the law, but I never have in my life read a bill or heard of a bill so grotesque in its terms, evil in its purposes, and vicious in its possible consequences as this bill would be if enacted.

Senator COPELAND. Outside of that it is a good bill?

Mr. THOMPSON. Outside of that it is probably a very good bill.

It was not until yesterday, Mr. Chairman, that I was able to find where the idea may have originated from any report of judicial legislative proceedings, anywhere, that would warrant the writing of a bill of this character. But after listening to Mr. Campbell I think I have discovered where they have found the judicial precedent. That is in the delightful story of Lewis Carroll concerning the trial of the Knave—under the chapter "Who stole the tarts." Probably the proximity of the Sylvian Theater to the Department of Agriculture where they played Alice in Wonderland brought the thought for the preparation and introduction of this bill. You will recall that in that case the king announced for the twentieth time that they should proceed with the trial, and the Queen interposed with the suggestion that the verdict should come first and the trial afterward.

Now, I am not going to discuss many facts here.

(Laughter.)

I think you misunderstood. If you had permitted me to finish my statement you would not have laughed. I mean I am not going to discuss the question of fact but rather to discuss the bill from the standpoint of the law.

There is a material difference between discussion of facts and a discussion of the law of the subject. This bill, as stated by more than one of the speakers, has departed in principle from everything which may be found anywhere in legislative procedure or judicial announcement, except, as I have already stated, as it may have been found in Alice in Wonderland.

It is proposed to grant such extraordinary power to the Secretary of Agriculture, which, in turn, means to the Drug Administration, that it may be well, Mr. Chairman, that we find out just about how far we should go. I take it that in approaching this bill the legislators, the Members of the Congress, will first inquire as to the necessity for the legislation; that, secondly, they will inquire, in the event they shall conclude there is necessity for legislation, as to the form in which the legislation shall take place; and, third, they will then very carefully investigate the powers which they may exercise, and, again, investigate how far those powers may be extended.

I think, Mr. Chairman, that I can well state the line of demarkation in the language of Judge Ranney of the State of Ohio, the outstanding figure of all time in that State as a jurist. In the case of *C. W. & Z. Railroad Co.* v. *The Commissioners of Clinton County*, 1, O.S. 77, Judge Ranney said:

> It is always legitimate to insist that any legislative enactment drawn in question is void, either because it does not fall within the general grant of power to that body, or because it is expressly prohibited by some provision of the Constitution.

Judge Ranney further said:

> The pure distinction, therefore, as between a delegation of power to make the law, which necessarily involves an authority or a discretion and as to its execution to be exercised under and in pursuance of the law. The first cannot be done; to the latter no valid objection can be made.

And that question, Mr. Chairman, confronts this committee and the Congress of the United States squarely in determining what is to be their attitude in respect to the extraordinary grants of power that

are read into this skeleton bill all the way from the beginning to the end; whether the Department is to be permitted to exercise a discretion as to what the law is to be. Without taking time to go into details, this grant of power can be found in a dozen places in the bill.

Now, it may be worth while to find out what the courts have said in this respect. You have been told a number of times when the present Food and Drugs Act was enacted, 1906; and the amendment, so-called, was enacted in 1912.

For months Congress gave attention to a bill which was prepared then, as now, by the Department of Agriculture, in which there was submitted then, as now, a so-called "chamber of horrors." After almost a year of consideration of that bill, in August 1912, the committee, upon the suggestion of Mr. Swagar Sherley, a former Member of the House of Representatives, reported an amendment dealing with the subject of therapeutic value.

Since the enactment of this law, as shown in the last notices of judgment issued in November 1932, 20,350 cases have been concluded in which I would say at least 99 percent of them were in favor of the Government. And I understand that before this series of more than 20,000 notices of judgment there was another series that preceded it in which there was an equal number—someone says there was not. Then, I withdraw that statement. Anyway, nearly a thousand notices of judgment in a year have been announced by this Department under the terms of the old act, which they say now is full of defects.

As against that there have been exhibited a few isolated instances, and if one reads this bill understandingly and with full possession of the facts, they will find what they have written in this bill the particular matters that have been covered in the few lawsuits which they lost.

They come here with a statement regarding "Bred Spred", after they had failed to prove it as an unwholesome article of food. They say "he did not exactly say it was a jam. He did not exactly say it was a preserve." The manufacturer did not sell it as a preserve or a jam. He sold it as "Bred Spred", and the verdict was for the respondent.

Why did they not call the attention of this committee to the fact that what they are aiming at is not merely "Bred Spred", but such substances as Kaffee Hag, Lee & Perrins Sauce, and Postum, and such preparations of that kind? It might well be said of Kaffee Hag that it looks like coffee and that it tastes like coffee. Still, they do not propose that the manufacturers of such products may not sell them under a distinctive name without disclosing the method or process by which they are made.

Senator COPELAND. Mr. Thompson, in that particular matter, Kaffee Hag is sold, is it not, openly as a substitute for coffee?

Mr. THOMPSON. Oh, granted. But, look, at the bill, where, if not sold under a recognized name, then the ingredients must be declared and the process may be required. The Secretary is empowered to demand additional information by regulations that may be imposed.

The CHAIRMAN. Is there any distinction between the mistaken impression bread spread would make to a housewife, where she thought that it was jam, and the sale of a substitute coffee which particularly put out as something which is a substitute?

Mr. THOMPSON. No.

The CHAIRMAN. The housewife taking those two articles, would it be as deceptive in one case as it would be in the other; one she would be deceived as to whether it would be jam, perhaps, and the other you feel she would be deceived as to whether it was coffee.

Mr. THOMPSON. It was sold as "Bread Spred." It was not sold as jam. I say that this bill reaches such manufacturers as Postum, and Kaffee Hag, and Worcester Sauce, and Lee & Perrins Sauce, and articles of that kind, which are sold without any question of their value as a food article.

Let us return to this first proposition as to the necessity of legislation. I am setting aside for a moment the question of advertising; I am setting aside for a moment the question of cosmetics; I am setting aside for a moment the question of foods. I will discuss it from the stand point of drugs at this time, and discuss the efficiency of this law which has been much berated here.

Over 20,000, I repeat again, of notices of judgments have been issued by the Department, showing the effectiveness of this law. I notice no reference was made to the ginger jake, which is, by the way, not a patent medicine. There are questions involved of fact; there are questions involved of law. I am going to discuss the legal side of it. Allow me to illustrate for a moment.

The paragraph designated "third" of section 8 of the old law provides that for the purposes of this act an article shall also be deemed to be misbranded, in the case of drugs, if its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

That is the third section in the case of drugs. In the first paragraph of section 8 there is the provision that an article of food or drug shall be deemed to be misbranded if a package or label bears any statement or any device which is false or misleading in any particular. I shall come again to the question of therapeutic value. But, for the present, advert to the first paragraph. The language of this paragraph is broad. For many years, and until the decision of the Supreme Court in the case of the *United States* v. *Johnson*, it was believed by manufacturers and distributors everywhere that the words "false or misleading in any particular included claims of therapeutic value.

Let us see what the Supreme Court of the United States has said about it, 265 United States 438. The Government is very fond of quoting that part of it which relates to statements which by indirection may be misleading. I notice they read very rapidly over the first part of this opinion. I quote:

> The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false, or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purposes of the act. The statute applies to food, and the ingredients and substances contained therein. It was enacted to enable purchasers to buy food for what it really is. That is the present law. The old law, the present law, is plain and direct and comprehensive in its statements, and condemns every statement, design, or device which may be misleading.

The CHAIRMAN. You would consider it desirable to continue that particular definition?

Mr. THOMPSON. Certainly. I desire to continue in the main all parts of the old law. I desire to vigorously, clearly, and positively condemn practically all the parts of this bill. Every statement and design which may tend to mislead are found in the present law. There is nothing in the field of food or drugs that may be stated upon the package or label which is not now covered by that act.

Let us turn to the matter of therapeutic value. You heard something yesterday about the inability of the doctors to agree about the "concensus of medical opinion." I was delighted when Dr. Emerson suggested that it should be "contemporary concensus of medical opinion." Contemporary with what? Contemporary with the medical opinion at the time merchandise moves in interstate commerce; contemporary with the time that it comes on the shelf of the retailer; contemporary at the time it is sold by the retailer; contemporary at the time it is delivered to the consumer; contemporaneous with today's opinion; contemporaneous with tomorrow's opinion?

I recall some years ago an incident that happened in your State, when the court of appeals of your State decided in certain particulars the so-called "cold-water ordinance", which was afterwards defended by Dr. Emerson, who was here yesterday, and I was in your office, to discuss the provisions of the sanitary code which you were preparing. We discussed with you the matter of claims of therapeutic value. You turned to your chief assistant, Mr. Salte, and this colloquy took place: "Mr. Salte, suppose that somebody had a preparation composed of 1/200,000th potency of Rhus tox.; what do you think would be its value in the treatment of rheumatism? What would you say? He said, "I would say it had no value." Then, Senator, you replied, "I would say it would be of great value."

The CHAIRMAN. I am afraid I am going to have the record against me.

Mr. THOMPSON. I withdraw that statement.

The CHAIRMAN. Oh, no; let it in, let it in!

Mr. THOMPSON. It showed your own understanding of the absence of a "concensus of opinion." I simply illustrate that to show that you have a broad knowledge and understanding of the difference of opinion which may exist.

In the agreed statement of facts in the appellate division of your Supreme Court and afterwards in the court of appeals, it was agreed that there is a wide divergence of opinion both as to the therapeutic or curative value of drugs, a divergence between members of the same school, as well as between members of different schools of medicine.

The CHAIRMAN. Mr. Thompson, I think the record ought to show here that as far as I am concerned, I doubt exceedingly if the Department is going to desire to enter into those matters which are of controversial nature in medical opinion. But it is very anxious to make it impossible to mislead the public into the belief that this, that, or the other product is capable of curing diseases which even the laymen know cannot be cured.

Mr. THOMPSON. I will get to that, if you will just leave me a little time in order to do it. I am talking about what the courts have said about these matters. I will get to that presently.

The CHAIRMAN. Go ahead and tell us now.

Mr. THOMPSON. I say to you now that so far as the package or label is concerned, those preparations which everybody knows are outside the realm of opinion, may now be taken care of on the criminal side and by libel for confiscation under the terms of the present act. We should leave out of this bill the provision "concerning the effect of such drugs which is contrary to the general agreement of medical opinion." I think that is too vague and speculative.

The CHAIRMAN. I figure that you are discussing now section 8, subsection A?

Mr. THOMPSON. Yes.

The CHAIRMAN. Is that the reference that you have?

Mr. THOMPSON. At the moment I do not have it before me, but I am talking about that provision. You say that you doubt, if we leave out the term "fraudulent" and if we make that to read "may be misleading, or which may be against the concensus of medical opinion" that the law will be ineffective.

The CHAIRMAN. One moment. Now you may proceed.

Mr. THOMPSON. I am talking about that particular provision.

The CHAIRMAN. You were speaking about that particular clause in reference to medical opinion?

Mr. THOMPSON. Yes.

The CHAIRMAN. There is no doubt about medical opinion as to the curability of tuberculosis, cancer, and some other things, is there? There is no question about that, is there?

Mr. THOMPSON. Yes.

The CHAIRMAN. All right; go ahead.

Mr. THOMPSON. I suspected that——

The CHAIRMAN (interpolating). You are going into the field of medicine, not of law.

Mr. THOMPSON. The section enters the field of medicine. I am referring to a statement of the Chief Justice of the United States, Justice White. Bear in mind that insofar as my association is concerned, the Proprietary Association, no one can remain a member who puts upon the market, any preparation offered for the treatment of a disease ordinarily incurable by the use of drugs. I want you to get our attitude, but I am answering your question categorically. You insisted upon it, did you not, Senator?

The CHAIRMAN. I won't insist upon anything, but I am glad you did answer it.

Mr. THOMPSON. Let us see: In the discussion before the Supreme Court of the United States, after a statement had been made in the O. A. Johnson case, no. 433, the Chief Justice wanted to know why the statement had been made—and they were discussing at that time cancer, and I quote from Chief Justice White's remarks:

"The CHIEF JUSTICE. Let me take a case I have in mind. I know a patient well who has a cancer, which three or four doctors, men of the greatest distinction and highest character, had diagnosed as such, and which got worse and worse. His people were all in despair, and they brought in an old country doctor. He had been riding around the country for 40 years, with his old saddle bags. He looked at the place and he said, "I think that ought to be cured." He went out to the drug store and mixed up a pot of ointment, which the three other physicians said was perfectly worthless, but he put it on the place, and, lo and behold, the place was cured. The others were mistaken, and he was not. Suppose those three distinguished gentleman had sat upon a jury, under that definition of this thing, and that doctor had put out that ointment, he would have gone to the penitentiary, would he not?"

It just shows what can happen in a case of that kind.

The CHAIRMAN. You say that is a Supreme Court decision?

Mr. THOMPSON. Yes, sir.

The CHAIRMAN. I just want to say to Mr. Campbell that you just might as well close up shop if we are going to have the Supreme Court tell us that cancer can be cured, because of any decision of theirs, I am inclined to dispute it.

Mr. THOMPSON. I am inclined to agree with you. These are the things that are not ordinarily regarded as curable. The question was categorically asked, and I had to answer it in this language.

I hope you are satisfied with my answer.

The CHAIRMAN. I am satisfied with the answer.

Mr. THOMPSON. Let us see what we have got.

The CHAIRMAN. One of the reporters says that the decision was upheld but the patient died.

Mr. THOMPSON. That, Senator, reminds me, of another humorism: A doctor was asked what ailed his patient. He said, "I do not know, but we will find out at the autopsy."

Probably the first time that this matter was raised—and I am talking now generally—I am not talking or arguing or speaking for the protection of these preparations as ordinarily regarded for treatment of diseases ordinarily regarded as incurable—they are now within the purview of the present law. The Supreme Court of the United States, have sustained informations and libels and postulated the averments that there is no known remedy for cancer or tuberculosis.

The CHAIRMAN. I would like to ask you a question: Are you contending that cancer and tuberculosis and Bright's Disease, and some of these other ailments which are mentioned in the bill are actually curable, and, therefore, that the wording should be left as to regulation; that the way should be left for proprietaries to be put out, advertising as a cure for such ailments?

Mr. THOMPSON. By no means.

The CHAIRMAN. Very well.

Mr. THOMPSON. Although, if I may be permitted as to the last named in the Government's list of diseases have——

The CHAIRMAN (interpolating). You are going to depend upon legal decisions rather than death certificates?

Mr. THOMPSON. No. I have a special reference now to whooping cough. I have in mind a particular case of the trial of whooping cough remedy: Mothers, witnesses, who said that they had used the preparation, and the children quit whooping. Those mothers knew their children had whooping cough. They knew when they quit whooping; the mothers knew that.

The rest of those particular items I do not know anything about. I think whooping cough should be out.

The CHAIRMAN. We have a higher authority than the Supreme Court. I can give you a higher authority than that, the Scriptures themselves: "Whereas I was blind, now I can see." That is in the Scriptures themselves. I just want to help your argument as far as I can.

Mr. THOMPSON. Thank you. My argument is based upon the theory that there is no lack of law for the punishment and destruction of the goods that are being introduced in interstate commerce and for false and fraudulent claims of value under the present law. That it is there now. That is my argument. That is my thesis. Whatever I may say is directed at that particular proposition.

The CHAIRMAN. As far as this item is concerned, if we were to continue the language of the present law you would be satisfied?

Mr. THOMPSON. If we were to continue the provisions of this act prohibiting the same things that were provided for in the so-called Sherley amendment, which resulted from Supreme Court decisions, and which resulted from the special message sent by Mr. Taft to the Congress of the United States; if they will preserve that language, and preserve to us our right in court, to try the issue there; give us our day in court, we will be quite satisfied. But, I am not willing that any language based upon the theory that there is such a thing as consensus of opinion and that a discretion be permitted to be exercised in an unhampered and unwarranted manner without the opportunity to our day in court. Let us take up Mr. Campbell's statement, and Senator McNary—I would like to address myself particularly to you in this behalf—it was claimed that any action on the part of the administration (the drug administrator; if I use the word "administration" I refer to that); that is arbitrary and capricious, that the courts can set it aside. Is that true? Let us see.

Nobody denies arbitrary action may be challenged. This bill drawn in a skeleton form with right to fill in the gaps; with the power to make regulations of any kind with the Secretary given the power to make regulations that he may deem necessary for the proper performance of his functions. With a mere basis of substance in the law, he may fill in with regulations. If you challenge the action of the administrative officers as arbitrary where do you get? The answer would be that the official acted with the provisions of the regulations. The only question then that can arise is whether or not the act was within the scope of the regulations. If that is true, it would dispose of the question of the arbitrary discretion.

The next question would be: Were the regulations within the scope of the act? And in the last analysis you would have to test while your business is being paralyzed, enactment of the provision of the law is within constitutional limits. In the exercise of a discretion the challenge would be only as to whether or not it was within the scope of the law. Let me again illustrate: Some years ago, under the power granted to the three secretaries, a rule was made in the department, without regulation, that in the event a substance is used in a preparation, which substance is a derivative of a substance required to be declared under the terms of this act, that the parent substance must be disclosed. The question was submitted to the Attorney General of the United States. The particular substance in issue was acetphenetidin, claimed to be a derivitive of acetanalid. The Attorney General of the United States said that the rule could not be maintained in the absence of a regulation but that inasmuch as it would effectuate the purposes of the Act, that the three secretaries should publish a regulation to that effect which regulation would be valid.

In other words, he suggested that a regulation be passed, which would cover the situation. Thereafter, a regulation to that effect was announced.

I think that the chemists here will recognize that acidphenetadin may be derived from a lead pencil, as was pointed out yesterday. The organic chemist can take a bit of blackboard and make a few marks on it, and they can show how organic substance can be produced. As a matter of practice, this substance is not derived from acetanilid, although it may be so derived.

The Supreme Court of the United States, in the case of the *United States* v. *The Antikamnia Co.*, upheld the regulation.

The CHAIRMAN. Just give us the citation on that.

Mr. THOMPSON. 231 U.S.S. 654. I can read it if you wish.

The CHAIRMAN. That is not necessary. We have the reference.

Mr. THOMPSON. In the case of *American School of Magnetic Healing* v. *McAnnulty* (187 U.S. 90) the Supreme Court of the United States, reviewing a decree dismissing a bill to enjoin a postmaster from carrying out an order of the Postmaster General directing the retention of letters, among other things said:

> The claim of the ability to cure may be vastly greater than most men would be ready to admit. Yet those who might deny the existence or virtue of the remedy would only differ in opinion from those who asserted. There is no exact standard of absolute proof by which to prove the assertion false and a fraud. We may not believe in the efficacy of the treatment to the extent claimed by complainants, and we may have no sympathy with them in such claims. Yet their effectiveness is but a matter of opinion in any court.

The CHAIRMAN. Mr. Thompson, certainly there is no question of doubt but what should be resolved in favor of the public.

Mr. THOMPSON. In favor of the public? The law ought to be written so plainly in its terms that he who reads it would understand its terms and if he were charged with an offense the person charged should be informed of the nature of the offense.

The CHAIRMAN. Mr. Thompson, I am going just as far as you desire to go in sentiment, in getting liberal interpretations to the administration of the bill. But, when that comes to these diseases which are generally known and generally considered to be incurable, it would seem to me positively indecent for the Government to make possible the sale of remedies which would encourage those people to go on with the treatment by the use of those affidavits when, perhaps, physical or something else applied by the legitimate profession of doctors would conserve or save their lives.

Mr. THOMPSON. Now, that, under the law——

The CHAIRMAN (interposing). You suggested a change?

Mr. THOMPSON. I suggest that I would ask that all drugs shall be deemed to be misbranded if it bears any statement or recommendation regarding the curative or therapeutic value in relation to cancer, diphtheria, tuberculosis, or some of the other diseases ordinarily regarded as incurable.

The CHAIRMAN. This bill has undertaken to name those diseases. If there are too many of them there, or if there should be any change in them, the Committee would be glad to have your suggestion. Have you put down as a general proposition that we must not interfere with an industry because somebody somewhere, even a Supreme Court justice, said that certain diseases were curable, when the consensus of opinion is to the contrary?

Mr. THOMPSON. No; I am willing to admit this. We have made no challenge to this particular section, but I do want to call your attention to one feature of it.

The CHAIRMAN. Page 13, subsection (c)?

Mr. THOMPSON. We have no objection to putting this in. None of my people sell this stuff.

The CHAIRMAN. Is that the reason you do not object to it?

Mr. THOMPSON. Sir?

The CHAIRMAN. Is that the reason you do not object to it?

Mr. THOMPSON. No objection; but whether I had any reason, you stated?

The CHAIRMAN. You said you had no objection because none of your people sold this product.

Mr. THOMPSON. No, no; I am sorry I said that. I was trying to convince you and the members of this committee that it was no personal interest I had in matters of this kind. There cannot be any interest on the very terms of our organization. If any of my people were to do that they cannot be one of us; any of my people, if they undertake to offer these things they are out of our association.

Let us look at line 22, page 13. Except that no advertisement shall be deemed to be a violation under this paragraph if it is disseminated to members of the medical and pharmocalogical professions nor other members of a scientific journal. In other words, it may be a lie and disseminated with safety in a scientific journal; but it is a violation when it is—it becomes false, if published in any other way, it runs against the law even though it may be the exact truth, if it is published in other magazines than those.

I told you that I had to look to Alice in Wonderland in order to find out what this bill meant. "Or published in a scientific journal." They are asking the Congress of the United States to make preparations which are printed, or, rather representations as they are printed, true or false, depending upon the character of the medium used in which it is to be published. This is the real interest that I have in that particular part of the bill.

Advertising, if used at the present for the benefit of the public by the Metropolitan Life Insurance Co., the articles with reference to prophylaxis against diphtheria, then might be a violation of law because it is published outside of a scientific journal. They are doing that not for the sale of medicines, but for the protection of the public.

You are familiar with that advertisement?

The CHAIRMAN. No; I am not.

Mr. THOMPSON. Of the Schenck—S-c-h-e-n-c-k, is that the way to spell it?

The CHAIRMAN. Shick test, is that what you have reference to?

Mr. THOMPSON. I may not get the word right, but I know what I am talking about. It would be a false advertisement by the Metropolitan Life Insurance Co., but you can tell a lie, if you do it in a scientific journal, under the terms of this bill.

The CHAIRMAN. That is another thing; how do you happen to have diphtheria in this bill?

Mr. DAVID F. CAVERS (professor of law, Duke University). With respect to the Shick test, that would not be applicable; it would have to be taken in along with paragraph (*c*). That is, plus one of the statements included in that paragraph, in the one above, and it does not affect the application of paragraph (*b*). When we deal with these advertisements under paragraph (*b*), inasmuch as this is not a treatment but a test, it would appear that it would be subject to paragraph (*b*).

Mr. THOMPSON. Now, my head is going around more than ever. The language is in the bill, and I can read the bill. The discouragement of public advertisement; I suppose some other advertisement of that kind if it was carried on by someone wholly independent of the man who wanted to sell his product, it would be an offense because it appeared outside of a scientific journal.

Senator MCNARY. I do not see why exception should be given to scientific periodical when the other journals of the country are forbidden to carry it.

Mr. THOMPSON. Neither do I. In the Johnson case, Mr. Justice Holmes, wrote the decision of the majority of that case (United States *v.* Johnson, 221 United States 488). The court had before it the question as to whether or not the statements appearing upon the package concerning curative effects were within the purview of the Food and Drugs Act. Mr. Justice Holmes said, among other things:

> We shall say nothing as to the limitation of constitutional power, and but a word as to what Congress was likely to attempt. It was much more likely to regulate commerce in food and drugs with reference to plain matters of fact, so that food and drugs should be what they profess to be when the kind was stated, than to distort the uses of its constitutional power to establish criteria in regions where opinions are far apart.

After that Mr. Taft, then President of the United States, sent a message to the Congress of the United States, and used, in part, language in substance, like this:

> Of course, as pointed out by the Supreme Court any attempt to legislate against the mere expression of opinion would be an abortive——

The CHAIRMAN. That was President Taft?

Mr. THOMPSON. Yes. I have given the gist of his thought as expressed.

The CHAIRMAN. Proceed.

Mr. THOMPSON. It was after that Congress used the language that representation of curative value should be both false and fraudulent. The Supreme Court of the United States had before it the question as to whether an offense could be charged under the sixth amendment of the Constitution of the United States.

In the opinion delivered by the present Chief Justice of the United States, then an associate justice, he stated, among other things, that Congress deliberately excluded the field where there are differences of opinion between schools and practitioners. It was plainly to leave no doubt upon this point that the words "false" and "fraudulent" were used. This phrase must be taken with its accepted legal meaning, and thus it must be found that the statement contained in the statute was put there to accompany the goods with actual intent to deceive, an intent which may be derived from the facts, but which must be established.

Thus, we have, briefly, the legislative judicial history of the Sherley amendment.

Let me now again say that anything which will protect the public against such preparations as cures for tuberculosis or cancer should it be done in an appropriate way, would be satisfactory, with the field of opinion entirely excluded.

Let me again say that on the question of food and drugs, so far as it relates to the package and label, we favor the present law; this law has no loophole except upon the theory that the Government is

forced to prove its case. It is my contention that the Government should be forced to do that. I know what is behind this bill. Let me, in closing, at this time refer to a book by James M. Beck, which is entitled "Our Wonderland of Bureaucracy." He says:

> The Lord Chief Justice of England recently published a book entitled "The New Despotism", in which he forcefully pointed out the subversion of Anglo-Saxon ideal of justice by the power of bureaucracy in England to make laws, interpret them, prosecute under them, and then act as judge and jury.

Referring to the bureaucrat of his own own country, he said:

> This course will prove tolerably simple if he can (A) get legislation passed in skeleton form, (B) fill up the gaps with his own rules, orders, and regulations; (C) make it difficult or impossible for Parliament to check the said rules, orders, and regulations; (D) secure for them the force of statute; (E) arrange that the fact of his decision shall be conclusive proof of its legality; (F) take power to modify the provisions of statutes; and (G) prevent and avoid any sort of appeal to a court of law.

All we ask of you is that you shall reserve to us the right for our day in court. It has been insisted that it is always being properly administered. In section 10 of the present law seizures may be made wherever the goods may be found. It resulted in seizures not close at hand, but in remote jurisdictions from Maine to Oregon, Minnesota to Jacksonville, Fla., and from New York to San Antonio, scattered all over the country, and it was not until this practice was stopped by the district court of appeals, which court declared that the practice of causing multiple seizures in taking of property without due process of law except in those cases where an emergency exists and drastic action is necessary. After that there was a cessation of the multiple seizures. One of the last was that of the Savoss which was previously an article known as "Save The Horse." I talked to the lawyer who has that case, and he says he has a winnable case, but the manufacturer has not money enough to try it. Where do you suppose they made that single seizure—bearing in mind that this firm is located in Binghamton, N.Y.? Do you think it was close by? No; it was in San Francisco, Calif. The preparation is made in Binghamton, miles away. They seized it at the very farthest end of the country from the location of the manufacturer. That does not show the reasonable exercise of power under the present law.

The law should be administered in such a way as to adequately preserve the right of trial in court. Such statements relative to reasonable enforcement as they have made are absolutely ridiculous and unsupported in fact. Seizure might have been made in some adjacent State, in New York, or Pennsylvania, or over in Connecticut, or Vermont, or New Jersey, where the respondent can make a defense to the claims. That is why we are opposed to the terms of this bill and that is why we insist that so far as the package and label are concerned, it is taken care of under the present act.

Let me say in conclusion that Professor Beale's analysis of the bill and his, Professor Beale's, draft of amendments to the old bill, which draft of amendments will enlarge the definitions to include clinics, which will include within the terms of the act cosmetics, which will provide against false advertising, but would save to the manufacturer, the party in interest, who introduces the product in interstate commerce, the right to his day in court. Such right is not in the pending bill. I, as one of the committee that sat as representative of one of the nine constituent bodies of the National Trade Conference, endorse

it. It will take care of every so-called defect except the power to exercise an untrammeled discretion. That is our position.

The CHAIRMAN. Thank you, and you will be likely to file a brief, I presume?

Mr. THOMPSON. I ask the privilege. I have spoken without notes. I know my diction has been poor, and I ask the opportunity to look over my transcript of this record of my statement before it is printed, and submit a brief as follows:

In a book by James M. Beck, entitled "Our Wonderland of Bureaucracy", I find under a chapter headed "Bureaucracy as Prosecutor, Jury and Judge" the following:

"The Lord Chief Justice of England recently published a book, entitled 'The New Despotism' in which he forcefully pointed out the subversion of Anglo-Saxon ideals of justice by the power of bureaucracy in England to make laws, interpret them, prosecute under them, and then act as judge and jury. Referring to the bureaucrat of his own country, he said:

" 'This course will prove tolerably simple if he can (a) get legislation passed in skeleton form; (b) fill up the gaps with his own rules, orders, and regulations; (c) make it difficult or impossible for Parliament to check the said rules, orders, and regulations; (d) secure for them the force of statute; (f) arrange that the fact of his decision shall be conclusive proof of its legality; (g) take power to modify the provisions of statutes; and (h) prevent and avoid any sort of appeal to a court of law.' "

FOOD AND DRUG BILLS PENDING IN THE CONGRESS OF THE UNITED STATES—AN ANALYSIS

By H. B. Thompson General Counsel, The Proprietary Association

I

I have tried to state what these bills will accomplish if enacted into law and the effect they will have upon the industry.

I think I can reduce the purpose and effect of these measures, if enacted into law, to a short formula:

(a) To prevent self-medication;

(b) To establish complete bureaucratic control over the manufacture, sale, and distribution of foods, drugs, medicines, and cosmetics;

(c) To secure, through the legislative body, a reversal of the decisions of the courts of the land; and

(d) To transfer the regulation of advertising from one forum to another, thereby effecting more drastic control and the probability of multiple seizures.

DRUGS

1. These bills are not amendatory of or supplemental to the present law. It is proposed to rewrite the Food and Drugs Act.

2. The term "drug" is enlarged to include devices and substances intended to affect the structure or any function of the body.

3. "Labeling" will include all matter accompanying the package.

4. "Advertisement" will include all representations of fact or *opinion* disseminated by any means other than by label.

5. All articles must bear a registered trade mark, which mark must carry a statement of the name, proportion and *properties* of ingredients.

6. A drug is deemed to be adulterated if, in addition to the requirements of the present law as to adulteration, it is or *may be* dangerous to health under the prescribed conditions of use. Note the words "may be." Under certain circumstances all drugs may be dangerous to health. By the same token, all drugs may be regarded as adulterated and their introduction into interstate commerce stopped.

7. An article of drug will be deemed misbranded if either in the advertising matter or on the label there appears any statement which (a) by inference would create a misleading impression; or (b) it is not in agreement with present-day medical opinion. Thus an unwarranted inference that statements are misleading or an assumption that they are contrary to present-day medical opinion will subject the goods to seizure and the manufacturer to prosecution.

8. Drugs will be deemed misbranded if any disease is mentioned for which the drug is not a specific cure, unless it carries a legend that the drug is not a cure.

9. The number of substances required to be declared has been increased over the requirements of the present act, and if such substances are used in the composition of a preparation, it must bear a legend that the preparation may be habit forming. The Secretary is empowered to add to this schedule.

10. All antiseptics are to be treated as germicides and comply with the standards of germicides.

11. There is a duplication with respect to formula disclosure. The Sirovich bill requires a statement of the name, quantity and properties of all drugs. Another provision requires the name, quantity, or proportion of the active ingredients to appear upon the label. The Secretary is authorized to require further information. This will, of course, mean complete formula disclosure.

12. Advertisement relative to a long list of diseases is prohibited. It is proposed to grant to the Secretary power to add to the list. This means that all public advertisement of all drugs may be ordered discontinued.

13. The Secretary is empowered to impose conditions requiring permits or licenses and officers or employees are to be permitted to inspect all establishments for the purpose of inspecting not only equipment, material, and labels, but *methods and processes.*

14. Violators of the act are subject to punishment on the criminal side and the bill contemplates fine and imprisonment for mere technical violation.

15. The word "person" includes partnerships, corporations and associations. The act of an employee is made the act of the corporation or association. Individual officers and directors are personally responsible for violation of the act by an employee of the corporation. Thus an officer connected with the company, having no personal knowledge of the violation, may be fined or imprisoned because an employee has been guilty of a technical violation.

16. The Government has the right to secure injunctive relief to prevent repetitious introduction in interstate commerce of articles of drugs. No provision is made to secure the manufacturer against repetitious seizures.

17. There is an interesting provision inviting voluntary inspection upon the payment, of course, of fees fixed by regulations. This will mean putting a Government inspector in everybody's plant.

The present Food and Drugs Act was approved on June 30, 1906. The Sherley amendment, dealing with therapeutic claims, was approved in 1912.

The courts have interpreted the provisions of the present law. These provisions are well understood and manufacturers have been able to adjust themselves to its provisions and requirements.

The enactment of this legislation will mean a complete readjustment, if indeed the business of manufacturing and selling packaged medicines can be continued at all. This is very doubtful.

The present law is wholly adequate. The courts have not always followed the interpretation placed upon the law by the Food and Drug Administration and its predecessors. This, in the main, is the real reason back of the introduction of these bills.

It has been contended that the control or censorship of advertising is necessary for proper enforcement. Cases of lurid and unwarranted advertising are said to have become common practice. In this behalf there is a disregard by the sponsors of the bills of the fact that there is adequate law to cover this situation. This law is being efficiently and vigorously enforced.

The pending measures seek to establish complete bureaucratic control and to give to the Department the power of life and death over the package medicine industry.

FOOD

1. The term "labeling" with respect to foods includes all matter accompanying the package.

2. The term "advertisement" includes all representations of fact or *opinion* disseminated by any means by other than the label.

3. In the proposed measure there is no protection afforded by the sale of a preparation under a distinctive name.

4. All of the regulatory provisions of the present law are included in the proposed measure.

5. Food will be deemed adulterated if its labeling or its advertising may create a misleading impression arising from ambiguity or *inference.*

6. An article of food is deemed misbranded if put up in what is known as a slack package; that is, if the container is so made as to mislead the purchaser, or if its contents fall below the standard of fill prescribed by regulations.

7. Formula disclosure is required, in addition to the specific provision requiring a statement of commonly used ingredients named in order of predominance by weight, except as to spices, flavors and artificial colors which may be designated without naming the spices, flavors or artificial colors. There is a general provision authorizing the Secretary to prescribe requirements for further information. This means or may mean complete formula disclosure.

8. The Secretary may place an inspector in the plant of the manufacturer to examine into, among other things, processes. He may place any manufacturer under a permit system.

9. Multiple seizures may be made for violation.

10. The measure empowers the Secretary to secure injunctive relief for repetitious introduction into interstate commerce of misbranded or adulterated articles of food, but affords no protection against multiple seizures by the Department.

11. The act of any employee is regarded as the act of the corporation. The act of the corporation is regarded as the act of any officer or director. Thus, an officer or director having no actual knowledge of the violation, is subject to fine and imprisonment, or both, for such violation.

12. The act contemplates punishment for technical violation of the act.

COSMETICS

The pending bills enlarge the scope of administration control to include cosmetics.

1. Cosmetics are defined as including all substances intended for cleansing, or altering the appearance of, or promoting the attractiveness of, the person.

2. Cosmetics are deemed misbranded if the labeling or advertisement thereof creates a misleading impression, either actually or by *inference*.

3. The Secretary is empowered to prohibit such substances as, in his opinion, may be injurious to health.

4. The Secretary is empowered to issue permits or licenses before cosmetics may be introduced into interstate commerce.

5. The Secretary is authorized to appoint inspectors to examine not only into the matter of materials used, but into the question of methods and processes.

6. Any officer of a corporation may be prosecuted and the products may be seized, which, of course, means multiple seizures, resulting from a technical violation by an employee. Thus, an officer or director may be fined and imprisoned because an employee has violated the terms of the act.

7. The repetitious introduction into interstate commerce of cosmetics may be prevented by injunction against the manufacturer. No attempt is made to protect the manufacturer against repetitious seizures.

8. There is an interesting provision providing for voluntary inspection of plants. This may mean the necessity of placing an inspector in plants, such inspector to be on the pay roll of the manufacturer.

II

Mrs. Oscar W. Underwood, after the death of the late Senator, published a book written by him entitled "Drifting Sands of Party Politics." In a chapter entitled "Bureaucratic Government" the Senator quoted Baghot as follows:

"Not only does a bureaucracy thus tend to under-government in point of quality. It tends to over-government in point of quantity. The trained official hates the rude untrained public. He thinks they are stupid, ignorant, reckless—that they cannot tell their own interest—that they should have the leave of the office before they do anything."

Let us examine the pending bills purporting to rewrite the Federal Food and Drugs Act, and observe how far the rights of the citizens are to be sacrificed on the altar of bureaucratic control, and see how the view of Baghot, adopted by Senator Underwood, fits into the picture:

1. Section 2, paragraph (g): The term "*Secretary*" means the *Secretary* of Agriculture. In turn this means the Food and Drug Administation, and hereafter in the references to the *Secretary* let it be borne in mind that it means in fact the administration.

2. Under the Sirovich bill (H.R. 6110) each article of drug must bear a trade mark registered in the Patent Office. The label shall state the composition of the drugs contained therein, including the ingredients, *properties*, and proportions of each drug used in such composition.

Also, each application for a trade mark must be accompanied by a statement from the Food and Drug Administration that the description of composition on the label complies with the Food and Drugs Act.

3. A drug is deemed to be adulterated if it is or *may be* dangerous to health under conditions of use prescribed in the labeling thereof.

The words "may be" mean dangerous to health in the opinion of the *Secretary*.

4. In the case of U.S.P. and National Formulary preparations, no drug is to be deemed adulterated for failure to meet the Pharmacopoeial or Formulary test if the label bears, in the manner and form *prescribed by regulations of the Secretary*, a statement indicating the departure from official standards.

5. Cosmetics are to be deemed adulterated if the use of the cosmetic *may be* injurious or if it bear any poisonous or deleterious ingredients prohibited (by the *Secretary*) or in excess of the limitation of tolerances *prescribed by regulations*.

6. Foods, drugs, or cosmetics are deemed to be misbranded if the labeling may *by inference* create a misleading impression—that is, such inference as may be drawn by the *Secretary*.

7. A food is deemed to be misbranded if such food is not defined in such terms as the regulations specify, or if it is represented as a food for which no definition of identity has been *prescribed by regulations*, and if the label fails to bear among other things the common and usual name of each ingredient thereof in order of predominance by weight. To this provision the *Secretary* may prescribe by regulation requirements for further information—that is to say, complete formula disclosure.

8. Drugs are deemed to be misbranded if, among other things, the labeling, *by inference*, bears a representation concerning the effect of the drug contrary to the *general agreement of medical opinion*—that is, the general agreement of medical opinion as determined by the *Secretary*.

9. A list of certain substances must be declared. Each must bear a warning statement that they *may be* habit-forming.

The *Secretary* may designate additional substances.

The *Secretary* may exempt any drug from the requirements.

10. A drug is to be deemed misbranded if its labeling fails to bear the common name of the drug, if any there be, and the name and quantity or proportion of each medicinal or physiologically active ingredient thereof.

The *Secretary* is authorized to require further *information*.

11. In addition to such drugs as are liable to deteriorate the *Secretary* is authorized to designate other drugs which *he* may find to be liable to deterioration.

12. An article of food, drugs, or cosmetics is deemed to be misbranded if any advertisement creates *by inference* a misleading impression. The inference of course is to be drawn by the *Secretary*.

13. Articles of drugs are also deemed misbranded if *by inference* any representation concerning the effect of the drug is contrary to the general agreement of medical opinion. Again, such general agreement of medical opinion is to be determined by the *Secretary*.

14. In the case of a list of diseases for which any advertisement for sale is prohibited, the *Secretary* may when he sees fit strike from the list. He may also add to it when *he thinks* self-medication for other than the named diseases is especially dangerous or patently contrary to the interest of the public health.

15. The *Secretary* may prohibit the use of certain substances in foods or cosmetics if *he* shall find that such substances *may be* injurious to health, taking into account other ways in which the consumer or user may partake of or be exposed to same.

A cosmetic is of course intended for external use. The substance may be prohibited by *regulations of the Secretary*, because he thinks that some part of the "stupid public" may drink it.

16. The *Secretary* may require the manufacturer to obtain a permit. He has the power to prescribe the conditions, the period of time for which such permit may run, collect the fees to be paid, and suspend such permit.

17. Permit holders must admit inspectors into their factories or establishments. Failure to permit the inspector to examine the plant is ground for suspension of the permit.

18. "In order *adequately* to regulate interstate commerce in foods, drugs, and cosmetics", inspectors are to be permitted to go into factories and examine, among other things, *methods* and *processes*.

19. When the *Secretary* has granted permission to some employee to visit your factory, if you should "stupidly and ignorantly" choose to stand upon your constitutional rights, the *Secretary* may ask the courts to restrain shipments until his decrees are complied with.

20. Carriers must submit records to designate officers of the *Secretary*, but by some lapse which evidently has occurred that there may be some constitutional inhibitions to the exercise of this power, provision is made that the evidence obtained shall not be used against the person from whom obtained. It is just too bad that the Constitition may stand somewhat in the way.

21. Examinations and investigations are authorized to be made by the *Secretary*, not for the purpose as in the present Food and Drugs Act of determining whether an article of food, drugs, or cosmetics is adulterated or misbranded within the meaning of the act, but "for the purposes of this act." Note the distinction.

22. The United States attorney to whom violations are reported must accept the findings of the Secretary without a further investigation.

23. Only in case *criminal proceedings* are contemplated, but not before *seizures* are made, is provision made for a hearing.

24. The *Secretary* may designate any officer to seize articles of food, drugs, or cosmetics without libel proceedings. If the *Secretary* has authorized such seizure, and an action is commenced by the parties injured, and a recovery had against the official, the fact that such official has been designated by the *Secretary* to make the seizure relieves him from liability of payment of judgment. The judgment is not to be paid by the superior officer, but out of "appropriations for the administration of the act."

25. All articles condemned by reason of the failure to hold an unviolated permit must be disposed of by destruction, even though the articles themselves are proper articles of commerce which may be relabeled in accordance with the law.

26. Publishers and advertising agencies are relieved from prosecution provided they furnish certain information to employees designated by the *Secretary*.

27. The *Secretary* shall publish periodically reports summarizing judgments, decrees, and proceedings instituted. He is also directed to disseminate such information regarding foods, drugs, or cosmetics as *he* may deem necessary to the interest of the public.

28. The *Secretary* is authorized to designate *supervisory* inspectors to examine plants, equipment, etc., and to fix the fees to be charged.

29. In addition to all of the specific grants of power above mentioned, the Secretary is authorized to prescribe such further regulations as *he* may deem necessary for the "efficient enforcement of the *functions* vested in him." Note the language. Not regulations necessarily within the scope of the act, not for the efficient enforcement of the act through the orderly procedure, but for the efficient enforcement of the *functions* vested in him.

In the event these bills are enacted into law, I think I may again very pertinently quote the language of the late Senator Underwood—"They have torn down a government of law and set up in its place the command of men."

III

I have said the purpose and effects of these bills, among other things, would be:

"(c) To secure, through the legislative body, a reversal of the decisions of the courts of the land;"

The courts are familiar with the *fact* that there is not now and that there never has been any standard of therapeutic or curative value. They have recognized that there is a difference of opinion between the different schools of medicine and between the physicians of the same school, both as to the physiological action and as to the therapeutic value of drugs, and as to the dosage.

In *American School of Magnetic Healing* v. *McAnnully*, 187 U.S. 90, the Supreme Court of the United States, reviewing a decree dismissing a bill to enjoin a postmaster from carrying out an order of the Postmaster General directing the retention of letters, among other things, said:

"The claim of the ability to cure may be vastly greater than most men would be ready to admit. Yet those who might deny the existence or virtue of the remedy would only differ in opinion from those who asserted. There is no exact standard of absolute truth by which to prove the assertion false and a fraud * * *. We may not believe in the efficacy of the treatment to the extent claimed by complainants, and we may have no sympathy with them in such claims. Yet their effectiveness is but a matter of opinion in any court."

Later the Supreme Court of the United States, in the case of *U.S.* v. *Johnson*, 221 U.S. 488, had before it the question as to whether or not statements appearing upon the package concerning the effect of the contents were within the purview of the Food and Drugs Act. The majority of the Court speaking through Mr. Justice Holmes, said, among other things:

"We shall say nothing as to the limitation of constitutional power, and but a word as to what Congress was likely to attempt. It was much more likely to regulate commerce in food and drugs with reference to plain matters of fact, so that food and drugs should be what they profess to be when the kind was stated, than to *distort* the uses of its constitutional power to establish criteria in regions where opinions are far apart."

The majority of the Court held that questions of therapeutic value were not within the purview of the act as then written at all.

The minority of the Court, speaking through Mr. Justice Hughes, with whom Mr. Justice Harlan and Mr. Justice Day concurred, dissented from the conclusions of the majority that "false and misleading" statements covering therapeutic value were not within its purview, but in the dissenting opinion Mr. Justice Hughes used the following language:

"But so long as the statement is not as to *matter of opinion* but consists of false representation of *fact*—in labeling the article as a cure when it is nothing of the sort from *any* point of view, but wholly *worthless*—there would appear to be no basis for constitutional distinction. It is not the less descriptive—and falsely descriptive—in the article."

Mr. Justice Hughes went on to say:

"I entirely agree that in any case brought under the act for misbranding—by a false or misleading statement as to curative properties of an article—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion. Conviction would stand only where it had been shown that apart from *any* question of opinion the so-called remedy was absolutely *worthless*, and hence the label demonstrably false."

It will be observed from the above opinion that the great court divided only upon the question of whether or not the words "false or misleading in any particular," appearing in the act, included claims of therapeutic value. The majority of the Court were of the opinion that to invade this field was to distort the constitutional powers of Congress. Upon other questions the minority were in practical agreement with the view of the majority except where the preparation is worthless and a statement of value is a representation of fact.

After the decision in the Johnson case, noted, the Congress of the United States enacted the Sherley amendment, so-called. This amendment reads:

"Third. If its package or lable shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent."

When this amendment was reported by the Committee on Interstate and Foreign Commerce, through Judge Covington, who was afterward Chief Justice of the Supreme Court of the District of Columbia, he, in part, said:

"In a criminal statute in which the gravamen of the offense is a false and fraudulent statement, the word 'fraudulent' is descriptive of the wrongful motive with which the statement is made, and is thus *capable of being established by the ordinary criminal evidence applicable to cases in which a proof of motive is essential.*"

Judge Covington further said:

"The proof of intent in the criminal law does not mean the metaphysical reading of a man's mind. Specific proof of intent is not necessary; it may be established by evidence of attending facts and circumstances, and therefore the Government can easily show that a false statement on a label regarding a drug is one from which fraudulent intent must be implied. *Conviction* in all *proper cases* will be consequently *comparatively sure.*"

After the enactment of the Sherley Amendment, in the case of Seven Cases *vs.* U. S. 239 U. S. 509, the Supreme Court had before it the question as to whether or not the Sherley Amendment was constitutional in view of the fact that in matters of therapeutic value the statute had entered the domain of speculation, and whether it operated as a deprivation of liberty and property without due process of law in violation of the Fifth Amendment, and *does not permit the laying of a definite charge as required by the Sixth Amendment.*

Speaking through Mr. Justice Hughes, the court stated, among other things, that

"Congress *deliberately* excluded the field where there are honest differences of opinion between schools and practitioners. It was plainly to leave no doubt upon this point that the words false *and fraudulent* were used. This phrase must be taken with its accepted legal meaning, and thus it must be found that the statement contained in the package was put there to accompany the goods, with actual intent to deceive, an intent which *may be derived from the facts and circumstances*, but which must be established."

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The contention that the Food and Drugs Act as written fails because fraud cannot be proven is fantastic. Fraud can be established, as stated by Judge Covington, by attending facts and circumstances, and conviction in *proper* cases are comparatively sure.

These decisions disclose exactly what the sponsors of the Food and Drugs bill have in mind in the proposed changes in the provisions of the law regulating the sale of drugs. It is apparent that they are quite dissatisfied and are wholly impatient with the decisions of the Supreme Court of the United States. That great court recognizes the truth—that there is a wide divergence of opinion with respect to the effectiveness of medicinal agents. It also recognizes the truth that fraud may be established in *proper* cases.

The courts can be trusted. Therefore the views of the court should not be swept aside, and Congress asked against the facts to declare that there is an agreement of medical opinion and to set aside the well-known rules of law, so that the guiltless as well as the guilty may be punished and property destroyed by the ukase of a satrap.

In a recent release, among other things, appeared the following language:

"Any intelligent conception of modern governmental functions must embrace the idea of effective consumer protection. The scope of such protective action must be progressively enlarged as population and the complexity of our social and economic life are increased. Thus, the protection afforded by the Federal Food and Drugs Act when passed in 1906 is radically insufficient today."

The decisions of the Supreme Court probably account for the contention that the present law is insufficient.

Courts other than the Supreme Court have disagreed with the interpretations both of the language of the act and of representations upon packages and labels insisted upon by the Drug Administration. The failure of the courts to agree with such interpretations does not necessarily mean that the law is radically insufficient. My view is that the action of the courts was based upon the idea that the *Administration* was wrong.

In the October 1933 number of Good Housekeeping, on page 94, appears an evidently inspired article by one Dr. Walter H. Eddy, in which he used the following language:

"The bill emanates from the office of the Secretary of Agriculture. It is primarily the expression of view of the public officials who under the direction of the present Chief of the Food and Drug Administration, W. G. Campbell, have had the burden of prosecuting violators of the old law. In their conduct of prosecutions designed to protect the consumer, these officials have met with situations that are not covered by the old law.

They have seen their efforts nullified and thrown out of court in certain instances, not because the violation wasn't real but because legally there was lacking provision necessary to enforcement of their measures of public relief and protection. * * * In its present form it" (the proposed measure) "expresses the viewpoint of the *enforcement* officers as to what they need in order to render more efficient service to the consumer, and to protect the Government from criticism of laxity."

Here we have it—

(a) The bill emanates from the office of the Secretary of Agriculture.

(b) It is primarily the expression of view of the Food and Drug Administration of what *it* needs.

(c) The officials have had *their* efforts nullified and thrown out of court in certain instances, not because the *violation* wasn't real but because *legally* there was *lacking provision* necessary to enforce *their* measures of public relief and protection.

It is a pertinent inquiry as to how there can be a violation without a prohibition. One has to study this suggestion for a minute before we catch exactly what is meant. It does not mean that there was any violation of law but that there was a violations of the opinions entertained by the Drug Administration.

It is assumed that the protection afforded by the present act is radically insufficient and that the efforts of the Administration have been nullified and thrown out of court upon the ground that there were lacking necessary provisions.

Such assumptions are not supported by the facts.

It is true that some efforts of the Administration have been nullified, and in certain instances their cases have been thrown out of court.

Cases are frequently thrown out of court because they are sometimes without merit, sometimes not well prepared, and sometimes not well tried.

In cases under the Food and Drugs Act the Government has lost in some instances for the following reasons:

1. The Government was unable to obtain conviction because suit was not brought in what Judge Covington describes as a proper case.
2. Failure upon the part of the Government to establish by the introduction of evidence applicable to the case the necessary facts and circumstances upon which wrongful motive may be proven.
3. Because the action was grounded upon a distorted inference rather than upon the fair import of the language used in the representations.
4. Refusal in proper cases to grant a hearing as contemplated by the provisions of the act.
5. Unsound interpretations of the language of the act as expressed by the Congress of the United States.
6. Neglect to make such records that a review may be had in courts of superior jurisdiction.

Again using the above a quoted languagee—under the present law the offense may be established by the ordinary criminal evidence applicable to the cases, and convictions are consequently comparatively sure when proper cases are brought, and such cases well prepared, and well tried.

NOTE: Except for the words "and fraudulent" italicized in the partly quoted opinion of Mr. Justice Hughes, italics have been supplied.

IV

THE NEW DESPOTISM

In a recent article which has been accredited to Prof. Rexford G. Tugwell, it is announced that the Copeland bill, S. 1944, has been designed to stop loopholes in the old act and to throughly "modernize" it.

It is further stated "it corrects or amends those provisions which prove ineffective in the light of judicial interpretations." That is, the loopholes are shown and the inefficiencies of the old act proven because the courts have not interpreted the act the way the Drug Administration would like to have it interpreted.

Therefore, if the courts can be ignored, the opportunity for judicial interpretation destroyed and complete control of the great food and drug manufacturing and purveying industry be placed in the hands of officials of the Department who may know little or nothing about the problems of manufacturing or purveying, the present law will be thoroughly "modernized."

The Food and Drug Administration likes to refer to a decision of the Supreme Court of the United States in the case of U.S. *v.* 95 Barrels, 265 U.S. 438. What the court decided in that case was that if an article is not the identical thing which the brand indicates it to be, it is misbranded, and by the same token if the thing is the identical thing it is indicated to be in that respect, it is not misbranded. In that case the Court in part said:

"The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false, or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act. The statute applies to food and the ingredients and substances contained therein. It was enacted to enable purchasers to buy food for what it really is."

Statements that are misleading, resulting from indirection and ambiguity, may be in violation of the present law, and if so the language used should be read favorably to the accomplishment of the purposes of the act.

One thing the Food and Drug Administration has constantly ignored is the following language used by the Court in the same case:

"The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive."

The Court is talking about the label requirements of the present law—that it is plain, direct, and comprehensive. Why then the "additional label requirements of the revision"? I'll tell you. It is that the Food and Drug Administration may be relieved of the necessity of proving their case in a court of law.

Courts are to be deprived of the opportunity of determining whether the language is ambiguous or by inference may be misleading. These matters are to be determined wholly by the Food and Drug Administration.

Again, in this article reference is made to poisons. The article states:

"The Government is forced to prove that an *added*, not a naturally occurring poison (for that does not count), is present in a *specific consignment of food* in such quantity that the food *may be* deleterious to health if consumed. It is therefore open to the manufacturer or shipper to prove that *this particular lot* of food *may not be deleterious* to health if so consumed. Each court case stands by itself and the consumer is inadequately protected."

The matter of added poisons has always been well understood. The word appears in the present law.

The Supreme Court of the United States in U.S. *v.* 40 Barrels, 241 U.S. 265, pointed out that the word "added" was used to distinguish between deleterious ingredients that might be found in an article and put there by man, from deleterious ingredients which might be found in nature's products as she produces them.

The difficulties which, in the opinion of Professor Tugwell, apparently result in the insufficiencies of the present law, is disclosed in the following language used by him in the article referred to:

"The Government is forced to prove" and "it is * * * open to the manufacturer or shipper to prove that this particular lot of food may not be deleterious to health if so consumed. Each court case stands by itself and the consumer is inadequately protected."

Why should not the Government be forced to prove the facts it alleges? Why should property be destroyed without such proof? If a particular lot of food does not contain added poisons deleterious to health, why should not the manufacturer be permitted to meet the charge and prove that his article is a wholesome article of food containing no such poisonous or deleterious substances?

I take it that what the good professor desires is that the manufacturer be not permitted to prove his innocence or that his preparation is a good food article.

The article contends that the consumer is inadequately protected if any appeal may be made to the courts. That is the sum and substance of it.

Another matter appearing in the Tugwell article to which I wish to advert:

"It does not give undue dictatorial powers to so-called Government bureaucrats. While it does grant the Secretary of Agriculture certain new authorities, it is very specific in these grants, and protects legitimate business interests effectually. Any attempt at the abuse of such authority by an arbitrary or capricious exercise of it will not succeed, because the courts, in the long run, refuse to sustain any requirements too far divergent from the ordinary community standards of good conduct and fair practice."

Notwithstanding that in one paragraph the statement is made that the grants of power to the Secretary of Agriculture are confined within narrow limits, in the very next paragraph appears the statement:

"A law must be sufficiently broad and flexible to effect the conviction of offenders whose conduct has fallen below the standards demanded by both consumers and ethical competitors. But if the language of the statute restricts itself merely to specific antisocial acts that its drafters anticipate, the discovery of loopholes in that law is inevitable, and the difficulties of its enforcement multiply endlessly."

The declaration that the grant is limited to a narrow scope is disposed of in the language which I have last quoted. The law must be so broad and flexible that the language is not restricted to specific violation for fear that loopholes may be discovered and difficulties of enforcement multiplied. Interesting, isn't it? In other words, bureaucracy is not to be limited. It is not to be confined within narrow limits. Powers must be so broad and flexible that these powers may not be challenged in court by an interested party who may feeel his rights have been invaded.

The Congress is now being asked to so rewrite the Food and Drugs Act that commerce in drugs be the subject of edict and decree and that action need not be limited to proper cases nor necessary care be taken in the preparation and trial.

NOTE.—Italics supplied.

V

The bills introduced declare among other things that their purpose is "to prevent the false advertisement of foods, drugs, and cosmetics."

There has been a persistent effort to show that there is no regulation of advertising in the field of foods, drugs, and cosmetics. You will see from what follows tnat there is both law and efficient enforcement. I quote from the annual report of the Federal Trade Commission, released December 12, 1932, for the fiscal year

ending June 30, 1932, and addressed to the Senate and House of Representatives of the United States, pages 46 and 47:

"During the fiscal year ending June 30, 1932, the special board concluded the investigation of and reported to the Commission 406 cases. Of these, 341 were against advertisers, 57 against publishers, and 8 against advertising agencies.

"In 45 cases the advertisers discontinued business, 12 more were forced out by post-office fraud orders, 3 discontinued false and misleading advertising before complaints were made, 42 cases were dismissed for lack of evidence or jurisdiction, 18 were referred to other divisions, 233 were disposed of by stipulation and prosecution of formal proceedings was recommended in 9 cases. In 44 cases investigations were completed, reported to the Commission, and await further orders.

"While it is impossible to state accurately the number of false and misleading advertisements that have been discontinued entirely or revised to check fairly with the truth, it is estimated that such number for last year, considered as being directly due to the Commission's activities, exceeds 20,000. The money saved to the purchasing public amounts to many millions of dollars."

You will please note the extraordinary activities of the Federal Trade Commission, together with their estimate that the number of false and misleading advertisements which have been either discontinued entirely or revised to check with the truth and resulting from the Commission's activities, exceeds 20,000.

In addition to the above, the so-called "Printer's ink law" prohibiting false advertising has been enacted by the legislatures of all of the States and the District of Columbia, except Arkansas, Delaware, Georgia, Maine, Mississippi, and Texas.

The desire for new legislation in this behalf is the wish to extend the new despotism.

The CHAIRMAN. Every effort will be made to accomodate everyone. The next statement that we have is that by Mr. Huston Thompson.

STATEMENT OF HUSTON THOMPSON

Mr. HUSTON THOMPSON. Gentlemen of the committee, having been before committees a number of times, I think I had better state specifically just whom I represent, so there will be no question as to my position. I am here as the executor and trustee of the estate of Carl H. White. The Carl H. White Co. is vendor of certain products. Carl H. White was the founder of the Health Products Corporation. This corporation produces a number of medicinal articles. Among those articles are what is known as "White's Concentrate," and a laxative chewing gum called Feenamint. In looking over the bill, it seems to me that there should be an amendment or inclusion or a proviso that will cover articles of this kind; that is, articles such as Feenamint being a laxative chewing gum, and "White's Concentrate." The bill, as it now stands, has a definition.

The CHAIRMAN. On page 2?

Mr. THOMPSON. Yes. On page 2 there is a definition of the term "drugs." On page 1 there is a definition of the word "food." Those articles of which I speak, and there are many others, of course, on the market of a similar nature, which are composed of both food and drug. So that so far as this bill is concerned, they are in a twilight zone, being covered by neither group.

It is my suggestion that we have a proviso by inserting the words, after the word "animals", on the last line—no, it is on line 11 of page 2—that will cover articles where the article is both a food and a drug. I have a draft of this proviso to follow the word "animals" on line 11 on page 2, in paragraph B.

The CHAIRMAN. Just read it.

Mr. THOMPSON. This is an amendment offered by Houston Thompson to this bill. I offer the following language as an amendment in the form of a proviso to be placed after the period following the word "animals" on the eleventh line under (3) of paragraph B, page 2, of the said bill.

Provided, That any substance or preparation which may be a combination of a food and drug shall be deemed and classified only as to food or drug, dependent upon its intended and/or actual use, which shall be clearly expressed on the carton containing the said combination, or on the label marking.

The CHAIRMAN. I do not understand the last part of that.

Mr. THOMPSON. That should be "which shall be clearly expressed in or on the carton containing the label marking the said combination."

My reason for that is this: This bill merely leaves a great discretion to the author of the bill or its administrator in connection with that, without being at all specific. It does not provide for it as specifically as would be desirable. For instance, if you turn over, for example, to the section covering tolerances, section 10, page 14, at the bottom of the page, you will find the subject of tolerances for poisonous ingredients in food and cosmetics and certification of coal-tar colors. Also you give discretion, as I understand this bill, to the Secretary to determine on the question, for example, of poisons and of anti-deleterious substances. If this were a food in all cases and there were used this element in there, as, for example, phenolphthalein, the question will arise as to whether there was injected a deleterious substance. You are in a position, if you leave the definition as it is now covering simply the question of food and drugs, that the strict interpretator would have the power over such a combination or such a product that might be a very serious one.

The CHAIRMAN. I see your point, and on page 2, between lines 11 and 12, you wish to have inserted the material which you have given us.

Mr. W. Bruce Philip, of Washington, D.C., counsel for the Association of National Retail Druggists, one of our 5-minute speakers, will now state his views in connection with this matter.

STATEMENT OF W. BRUCE PHILIP

Mr. PHILIP. The National Association of Retail Druggists has for over 25 years represented the interests of 60,000 retail druggists in the United States.

We wish to subscribe to Dr. Beal's analysis of the Tugwell bill.

We wish also to subscribe to the suggested amendment to the present Food and Drugs Act that will be presented.

Briefly, the problem of the retail druggist is quite different from the problem of the large manufacturer. On the druggists special subjects I would like to give you a little information and some experiences.

It is easy enough to say that if the laws or regulations are not satisfactory you can go to court. The average retail druggist cannot afford to go to court, in fact, the druggists, I should say, over 59,000 of the 60,000, will be forced to accept the regulation, regardless of whether they are in accordance with the law or in accordance with their rights. It is almost impossible for the average retail druggist to protect himself against the regulations. This bill, as I read it—and I have read it carefully—is a skeleton bill that gives to the

authorities, the Secretary of Agriculture and his assistants, full power to regulate food, drugs, and cosmetics.

One experience that we had under a law that was wiped out this month (the eighteenth amendment), was a case in point where undoubtedly not only our constitutional rights, but the services to a large group of people were affected. We raised $4,000 to carry the case to the United States Supreme Court. We did the best we could. The Government informed me that they were very happy to have the point involved decided by the Supreme Court. When the case came to the Supreme Court, the Government's attorney found that we had failed to join the Collector of Internal Revenue and therefore we lost our case. The point was never decided and unquestionably our rights were affected until the eighteenth amendment was repealed. The enthusiasm that people get in the Government employ often carries them beyond the point of necessity. Inasmuch as this is a bill depending upon regulation rather than the wording of the bill we cannot understand what it means. Let me tell you of an instance that occurred showing how important regulations are. Some of you may be familiar with this regulation. This regulation existed for years after it was written.

I think you, Dr. Copeland, may have had some personal experience in connection with this regulation. Inasmuch as I am a pharmacist. At that time I was in my own drug store, and we were filling prescriptions for a great many tuberculosis patients. I, personally, was working at the prescription counter and I was familiar with the regulation I will tell you about. It was a narcotic regulation. Let me, before I go further, say this. Our association is behind the narcotic regulations; we will go to almost any degree to support any officer in the enforcement of narcotic regulations, and they will so tell you. This regulation required that when a narcotic was prescribed for a person with an incurable disease the name of the disease had to be written on the prescription. It was undoubtedly a good intention. They wanted to protect the public from receiving lots of narcotic prescriptions or to prevent a few physicians or a few pharmacists abusing the law. But actually what did this regulation do? The doctor handed the patient a piece of paper and the patient could read his own death warrant. The regulation made the prescription the patient's death warrant. I, personally, have seen people dejected and in despair with their narcotic prescription in their hands which said to them, "You must die." It was not the law; it was a regulation. It took 2 or 3 years to have that regulation changed. That is a long time.

We could have gone into court, but we had no money to go into court. Instead, we protested, and we had to protest time and time again. Finally, the regulation was changed.

Our members have to deal not with men like Mr. Campbell, not with the people here in Washington, but with the hundreds of people that are lesser employees in the Government service. Many are inexperienced. We have untold problems with these inspectors and enforcing officers. The first time we had an insecticide law in California, we had tooth paste and hair preparations tied up in one district for a week or two until we could get our committee together and go to Sacramento and have the regulations changed and new instructions given to the inspectors. That is the way regulations

were carried out in an insecticide law. We had to have inspectors told how regulations were to be carried out under an insecticide law. If this law is to be effective, and our idea is to have laws effective we must have a similar Tugwell bill in every State. To pass an entirely new law that is different from 48 similar State laws, must mean the repeal of 48 present State food and drug acts and the passing of a bill like the Tugwell bill in every State. This is a very difficult proposition. It is far better to take the present law and amend it and then have State laws which are now following the present Food and Drug Act, amended. As I said, S. 1944 is a skeleton bill with full power in the Secretary of Agriculture. Are we going to have 48 States laws with the power in each State in the State secretary of agriculture? Are we going to have any uniformity? Under these conditions, are we going to have anything that is a protection to the public and that is satisfactory to the public? I doubt it.

We have here in the S. 1944 an example of the Department's enthusiasm, and I do not blame Mr. Campbell for his enthusiasm; I do not blame anyone working for a law like this, being enthusiastic, but in the definition of confection, in his desire to punish those putting metallic substances in candy he has written S. 1944 so that it would destroy the entire chewing gum industry. It was not the intention of Mr. Campbell or Mr. Tugwell to do that, and I am sure the law will be modified. But, in their enthusiasm to reach one or two or three problems they have written provisions that have a very far-reaching effect. In their effort to reach these cases which are asserted to be dangerous, the bill has been written without regard to how far many provisions will go. I mean by that, that in trying to enforce this law aginst such things as these metallic trinkets that do not represent the average condition, but are more or less far fetched, that the far-reaching effect of the regulations and the laws will be difficult to be lived up to in ordinary practice.

The CHAIRMAN. You will remember that Mr. Campbell suggested an amendment to that particular section.

Mr. PHILIP. He did, and that is the point, Senator Copeland. Laws are prepared so that we may come here and protest and have the law rewritten, but a regulation is issued over night. We do not see the regulations until they are handed to us and they have the force of law. If the definition of a confection was a regulation it would wipe out the industry of chewing gum until we could go into court or reach the proper person here in Washington and have the regulation changed. What we want, Senator, is this: We want a law we can understand. We think we are right in wanting it, and we think we are earnest in our intentions in coming here, to ask for a law that we can understand, that we can read, understand, and follow as a part of our business. We have the difficult problem of serving the public and we must know exactly what we should do.

I object, both as a citizen and in the name of the association, to placing a great deal of power in the hands of any Government bureau. Congress meets every year. We will go with you or with Mr. Campbell or anyone else in an endeavor each year to have laws strengthened and modified, but if the law is so written that we have regulation after regulation, and it takes 2 or 3 years to change that regulation, we are simply at a disadvantage in serving the public. There is one more thing I would like to call to your attention, that is the voluntary inspection service, section 22, page 29. That, in my opinion, is not a voluntary inspection service, it is a compulsory inspection service and if it is to be enacted in every State, it means that in each State we will also have compulsory—called voluntary—inspection service. Can you imagine, Senator, when one manufacturer says, "I have been approved by the Government", another manufacturer daring to say, "I have not been approved by the Government." I do not like the principle; I do not like the members of the industry being taxed in the way of extra fees that are not designated and not known. It gives every bureau, if this principle is good, opportunity to go to the Congress for their appropriation, and then go to the industry for another appropriation in the way of a tax for services. If we have two sets of fees, one from the State, and one in the form of Federal fees, in addition to the 18 or 20 or 30 more individual State taxes, it is going to amount to a considerable amount of money.

The CHAIRMAN. Would you suggest cutting out that section entirely.

Mr. PHILIP. I would consider, certainly, that you can figure some way for that inspection, if that inspection is of value to the public, the public ought to pay for it.

The CHAIRMAN. It should be universal?

Mr. PHILIP. It should be universal if at all. One other thing I overlooked, Senator. That is the fact that the statement made in any lay publication or in any publication that is not to the physician a scientific publication is false on its face. We have 60 or 70 drug trade journals. These are not scientific publications in the sense that the American Medical Journal is. They are not to the physician or to the pharmacologist, but they go to 60,000 druggists that serve the physicians in the United States, and serve the people. I do not believe under the provisions of S. 1944 drug journals are strictly scientific publications. Mediums for many prescriptions could not be advertised to 60,000 druggists through our drug trade journals.

The CHAIRMAN. I did not understand your last comment.

Mr. PHILIP. I say I do not believe that under the provisions, under the article dealing with the strictly scientific preparations for these prescriptions, under this article, that they could be advertised through our 60,000 trade journals, but the same thing could be brought to the attention of the public through scientific magazines like the Scientific American or maybe Popular Mechanics, if that is considered a scientific publication. I call that to your attention principally for this reason, since the drawing up of this bill is so full of conclusions that must be analyzed and reanalyzed, that I feel as though our contention is correct and we should amend either the present Pure Food and Drug Act and if it were my privilege to write the great men of America, I certainly would put Dr. Wiley, Dr. Harvey Wiley and his associates, way up in the head of the list, because I regard him as one of the great men of this country.

The CHAIRMAN. You and I are one in our admiration of Dr. Harvey Wiley. He was one of the finest.

Mr. PHILIP. I desire to have inserted in the record at this point a brief which I have prepared. The brief follows:

The National Association of Retail Druggists is an organization over 30 years old. This association has something over eight thousand and odd individual paid-up members and by affiliation of 48 State pharmaceutical associations and the

District of Columbia Pharmaceutical Association has an affiliated representation and membership which bring the total number of members above 30,000.

There are approximately 60,000 retail drug stores in the United States, therefore, the National Association of Retail Druggists represents over half of the retail drug stores in the United States.

The disastrous provisions of this bill could wreck the industry of pharmacy. To you who are interested in protecting the consuming public listen please to the position of words, phrases, and clauses of S. 1944 (also including the corresponding H.R. 6110) which would control 60,000 retail druggists besides numerous other people who have the right to live.

I. The druggists feel that if the law does not define adulterated, misbranded, false, etc., with words more definite than opinions how can a manufacturing druggist or a retail druggist know what the law is? He cannot.

II. How can Members of the Senate or House or any committee vote intelligently on any measure that does not tell what it is going to do? This proposed legislation is left to regulations which are not yet made and which may be changed at any time.

III. Is it desirable to have standards for foods, the same as those standards that are subscribed for drug substances? (The same requirement?) No law should demand that they be the same; as, salt, olive oil, etc. (The United States Pharmacopœia and the National Formulary fixes a standard for many items used both as medicines and foods.)

IV. Druggists must know what is a "devices"? Where does power to control "devices" begin and end? In accordance with the far-reaching scope of this bill (see section on advertising) I cite as an example, surgical instruments used by physicians for operating on "bone diseases", "cancer", and "tumors" which are mentioned in the law. These could not under the proposed bill be mentioned orally or by writing or in drug-journal advertising. All information to industrial establishments regarding these surgical instruments would be prohibited whether legitimate or not.

V. Druggists ask, How can a ruling made by the Secretary, which is wrong, be modified? If industrial experts refute it under regulations when the law limits the word "Secretary" to one person?

VI. Druggists want to know, "What is an opinion?" If a druggist has thousands of dollars invested in accordance with the opinion of one Secretary of Agriculture, and that Secretary changes his opinion, the fact remains the same, or if another Secretary of Agriculture is appointed with another opinion, who refunds the money when the druggist loses his investment?

VII. What good to a pharmacist is his United States Pharmacopœia or National Formulary, if the "limits of tolerance" on food products included in the United States Pharmacopœia or National Formulary may be changed by the Secretary of Agriculture?

VIII. (c) of section 3 is so carelessly drawn that it would stop the sale of gum because it contains chickle, which is a nonnutritious substance, popsickles, all-day-suckers, chocolate bananas, and all confectionery without end, and any that have a stick for a holder. Does not this show that the Secretary of Agriculture proposed a disastrously worded bill that was supposedly written in his department by his experts? Will not the present Secretary allow regulations to be issued that may destroy a branch of industry? What guaranty have the industries and the druggists that another Secretary will be more far-sighted, and write more clearly worded regulations than this one has in this bill?

IX. How are druggists going to have a standardized definition of "dangerous to health" when human bodies have idiosyncrasies to medicines? Individuals interpret words, directions, labels, and advertisements differently.

X. Druggists want to know, will the word "simulate" prohibit the using, as part of a title to their preparations of any drug which is mentioned in the United States Pharmacopœia or National Formulary? Example, Browns Cinchona Mixture.

XI. The pharmaceutical profession wants to know why the Secretary of Agriculture can arbitrarily change the "lists or methods of assay" of the United States Pharmacopœia or the National Formulary.

The bill (S. 1944) gives no guaranty that the Secretary will abide by the decision of, or call in, experts equal to, or superior to those who have already determined the "lists or methods or assay" in the United States Pharmacopœia or National Formulary.

Will new lists be adopted if the Government loses its case in court whenever there was an honest difference of opinion between the Secretary and industry, thus in fact revising the court's opinion?

If whenever there is an honest difference of opinion between industry and the Secretary, and the Government loses its case, does not S. 1944 permit the Secretary to change the disputed standard which will then revise the decision of the court.

Practically, this means regulations issued by the Secretary must be accepted by industry.

XII. Druggists ask, "When is a cosmetic injurious"? Who is to be the standard, man or woman the Secretary of Agriculture will measure cosmetics by or on?

XIII. Druggists want to know, when will the limits of tolerance be stationary? Could not changing tolerance exclude one manufacturer and favor another?

XIV. Druggists ask, why is there not a way to arrive at reasonable variations, and have them prescribed by the law, and not left to one man?

XV. How can a druggist be sure he is not "creating a misleading impression" when numerous sales are made over the telephone.

XVI. With thousands of illiterates as drug-store customers, in the United States, how can a retailer be sure any label is "readily intelligent to the purchasers" of his wares.

XVII. Druggists want to know if the words "misleading the purchaser" would not be a problem between the individual and the manufacturer, and would there not have to be 125 million of such opinion ascertained if the manufacturer wanted to be sure that he was not misleading someone.

XVIII. It is of vital importance for druggists to know what the words "further information" on the label means. Might not this require that full formular disclosure be made on the label?

XIX. This bill is so far reaching that druggists under the terms of it must know exactly the strength of each and every drug, medicine, or food, which they sell in terms of a pallative or a cure. When we come to the section on advertising this law becomes more drastic and far reaching.

As the word "drug" inclues preparations (combinations) this problem becomes highly complex.

No text books, even standard books, now used in colleges can be relied upon for this information.

XX. Suppose a pharmacist wants a medical opinion on a preparation he has made. Could he go to those standing highest in his community or State; or would he have to obtain that opinion through only those designated and approved by the Secretary of Agriculture. Would this not give the Secretary of Agriculture's medical experts a monopoly on all information given out to the public by label? Would not this increase the price of such an opinion?

XXI. Pharmacists are much concerned over the confusion that may arise over the fact that the common names of a drug are required to be placed on labels, because a common name in one part of our vast country may not be applied to the same drug in another part of the country.

XXII. Druggists will want to know if a package of medicine is placed in a peculiar-shaped bottle to give it distinction (and individuality), and contains 4 ounces and is so labeled, must the package be changed if a customer claims it has misled him as to quantity?

XXIII. Manufacturing druggists want to know how they are going to comply with section 8 (j). Is this a laboratory standard, or are human beings to be used as a standard? What factors of application and pathological conditions must be met?

XXIV. May a druggist put any advertisement in any publication, or say anything or write anything, about a drug when the bill says "an advertisement" "shall be deemed to be false if in any particular" it "creates a misleading impression"?

Under this wording could a pharmacist who was working with a group of scientists, put his name to any article which resulted from the scientists' research and which dealt with any drug, unless the article was approved by physicians chosen by the Secretary of Agriculture who might announce a general agreement of medical opinion? If he did, might he not be liable to fine and imprisonment?

XXV. District of Columbia druggists want to know if section 9 (c) does not prevent them giving information over the telephone in the event of emergency or in any other way suggesting emergency use of medicine or application for dis-

eases enumerated. (Read the word "Advertisement" according to its definition. (Sec. 2 (1), p. 3, lines 15–17.)

XXVI. Druggists want to know: What is the standard for the word health? Is health the same for each individual?

XXVII. Pharmacists want to know if an inspection of methods, processes, finished and unfinished materials does not mean letting inspectors know all the details of manufacture which have been perfected after years of study, experience, and research.

XXVIII. Druggists want to know if a crook cannot avoid section 14 by having a continual change of sales agents within the State.

XXIX. Druggists want to know if compulsatory destruction of merchandise under section 16 (d) (last sentence) would be enforced against merchandise innocently purchased if they could be reconditioned.

XXX. Perchance a druggist should write to some member of his family or to another druggist in another State, something contrary to the Secretary of Agriculture experts medical opinion. Then, under section 17 (3), would he not be criminally liable?

XXXI. Often druggists are directors for corporations. Should a board of such directors pass an appropriation for advertising, and part of this money which is paid for an advertisement be declared later on to be misleading (by the Secretary of Agriculture), would not each and every director be criminally liable and subject to fine and imprisonment?

XXXII. Druggists want to know if section 19 is not really substituting for the former plan of multiple seizure, the closing of a factory by injunction, by the Secretary of Agriculture. Multiple seizure is unfair in many instances, and the Secretary of Agriculture seems determined to put out of business those with whom he differs, when he so desires.

XXXIII. What redress will a druggist have against the Secretary of Agriculture if his name or business is ruined, should the Secretary of Agriculture under mistaken fact issue unfavorable publicity under the last sentence of section 21?

XXXIV. The amount of tax for service under section 22 must be stated in the bill. Over half of the sixty thousand druggists are to be found in the red today. If they are to contribute to the support of a bureau of the Department of Agriculture, how much in dollars will this cost?

XXXV. Druggists want to know, will the Secretary of Agriculture expect 48 States to also have a voluntary inspection service? If so, how will conflict of service be avoided? Can a druggist avoid paying for Federal and State revenue a double tax for one purpose?

XXXVI. Pharmacists want to know why the finding of fact by the Secretary should not depend on substantial evidence before it is conclusive?

XXXVII. How much greater will a druggist's liability be under section 24 than under the common law, and how much less will a Government official liabilities be under section 16 (b) than under the common law?

The word "Regulations" appears in S. 1944 33 times, and gives thereby power to the Secretary of Agriculture and this power is not limited by the bill. This power given to the Secretary of Agriculture is more far reaching than the known provision of the bill.

Druggists as well as Senators and Members of the House cannot possibly know the scope of this bill. Under S.1944, an act one day may be legal. The next day, the same act may be a crime. The reason for this might be an "inference" an "ambiguity."

Many criticisms made by Dr. J. W. Beal, of S. 1944, to be found in the minutes of the hearing before the subcommittee, have been purposely omitted from this brief. Dr. Beal's brief is concurred in.

The retail druggists are not trying to split hairs. Years of experience with Federal Government officials has given us many sad experiences. We could cite incident after incident when the hair splitting has been on the Government inspector's side, especially when they are young and inexperienced. These often desire to make a record.

New laws make much trouble through misinterpretations of their wordings and through interruption of business, pending court decisions, which decisions often take years of litigation.

An amended food and drug law has been suggested instead of S. 1944. It is not only possible to amend the present law, but is the thing to do at this time if any changes are to be made. As the attorney for the National Association of Retail Druggists, I recommend an amended food and drug act, instead of S. 1944.

The CHAIRMAN. I will now call on Mr. Charles M. Cox, of Boston.

STATEMENT OF CHARLES M. COX, BOSTON, MASS.

CHARLES M. COX. My name is Charles M. Cox, and I am president of the New England Grain Products Co. I am representing the American Feed Manufacturers' Association. We are coming here to ask for a word in regard to the food we furnish for animals and poultry. Ours is a very large industry, sir; probably larger than people appreciate. For example, about 300 carloads a day of feed roll into New England from other States. My own concern handles 50 cars per day. That does not include anything for food for human consumption. It is entirely food for animals and poultry. I might say that, with certain exceptions, we are in sympathy with this bill as it is being introduced. I might say that we might cause some enlivenment in this meeting by introducing some samples of our chicken feed, but I feel it would not meet with the response or receive the welcome accorded other products introduced here today.

The CHAIRMAN. If you will come down to Broadway, you will find plenty of candidates.

Mr. COX. We are accustomed to Government control of our business; definitely so. We are controlled possibly more than any other industry, and we are controlled by the State experiment stations; we are controlled very closely. Our own concern manufactures many specialties, and many more are placed on the market in our line by competitors. Our concern employs five specialists who are studying all the time how to improve our products so that we may improve the general line of goods that are sold by us. We are working with experiment-station men at all times. We look for you to produce a bill which we can favor. We have very little opposition to your bill, sir. I might state three instances, very briefly.

Page 4, lines 16 and 17, we would like to add the words "in a deceptive manner." That particular phraseology regarding the increasing of bulk of food—it is very often necessary for us to increase the bulk of our foods for cattle. We do it largely with bran, but we would like to have the words introduced "in a deceptive manner."

On page 9, line 6. I am trying to say what I have to say just as rapidly as I possibly can so as to finish within my time.

The CHAIRMAN. You will be given time.

Mr. COX. I am trying to go pretty fast so as to get done. Page 9, line 6. "In the order of predominance by weight", would lead toward an open formula. I do not think it is called for and we do not think it is necessary in our line of business. There are reasons why in certain periods of certain years some kinds of grains or by-products are low in price and it is good business both for manufacturer and farmer to vary slightly our formulas in accordance with the prices. We do this in accordance with the experiment station opinions. We think if this clause were allowed to remain in, it might be an injury to people like ourselves where we have been operating 30 years to build up a reputation for our formulas which are successful. It opens up all of these avenues of information which gives anyone the very knowledge that we have taken years to acquire.

The CHAIRMAN. Just a minute, Mr. Cox.

Mr. COX. I am taking all the time you will let me.

The CHAIRMAN. This is not coming out of your time. It is coming out of the audience's time. Predominance by weight; would you

have any objection to enumerating the articles in their order by weight as long as you would not be required to tell the exact proportion of each one?

Mr. Cox. We would rather not. We find people just coming into this business, and they would take advantage of that to use our formulas. I might say I am not nearly as young as you are.

The CHAIRMAN. I think we are about the same age.

Mr. Cox. I beg your pardon, I am past you a lot. We have been building this business up and we have been playing this game for 50 years and—no, we have not, it is only 30 years, that we have been in this special-feed business. We have been in the grain business for 50 years. We have been in the prepared-feed business for 30 years. It is a comparatively new industry trying to develop itself further, and I might say that we have grown with the business from the very time that it started. We are with the old timers in this business. We do not have food for human beings. I might say that we feed the hens and the chickens more wisely than we feed human beings.

The CHAIRMAN. I agree with you.

Mr. Cox. If I knew how to feed myself and my family as well as I know how to feed hens and chickens, I think I should be a very able man, sir.

The CHAIRMAN. You would know how if you would listen to me, Mr. Cox.

Mr. Cox. I have, sir. Did I answer your question about the order of predominance?

The CHAIRMAN. Yes.

Mr. Cox. One more suggestion I would like to make on page 15, line 11. About definitions and standards for our foods. I want to impress once more that we are conducting a very enormous industry. I want to say that we are people who furnish possibly as much in dollars and cents as all of the human beings buy in this country or consume—probably not that much, but it must run up pretty well, I am sure of that. There are no exact figures available. When you go into the standards of our industry, I think it is very doubtful if they can be made correctly by the Government. We have many relations with State experiment stations and are also known to Dr. Campbell. We do not know Dr. Campbell as well as we would like to, but we do know his assistants, Dr. Dunbar and Dr. Bidwell, with whom we are having conferences in our line of industry, from time to time, and I think they will agree with me that to make a standard for dairy feed is extremely difficult, exceedingly difficult, in fact, because the variations in conditions are so great. I am not talking about candy. Candy is entirely different from cattle feed; I am talking about hens and cows and chickens and hogs. In California there is almost no roughage outside the irrigated area; and down South roughage is pretty poor while cottonseed meal with its high protein content is low priced, and in the North, in New England, we have fair pastures; but in the Middle West they have fine pastures. Comparatively speaking, they are very fine. You cannot make a standard to cover the whole country; that is, we do not think you could. You would have to have a great many standards. I will say in closing—I can say a lot more, but I do not want to take up your time—I wish to take the liberty of making two or three suggestions. You have asked for them. I would like to suggest that you divide this bill and have a

bill for human beings and a bill for cattle feeds. Also, we would like to ask you to divorce cosmetics and drugs from anything relating to food.

Senator MCNARY. You mean that the bill should be separated into parts, two separate heads, one having to do with drugs, and the other having to do with foods?

Mr. Cox. Yes; or separate bills. I am not a legislator, but any way is satisfactory to us to get away from drugs and cosmetics and human foods.

Senator MCNARY. That has been suggested in a great many wires and telegrams that have been sent to me.

Mr. Cox. We would like to submit a brief. I do not know as you will ever read it. We want to favor a bill. We are living up to the law now, and we propose to live under it. It helps us. It helps to keep out anyone who is not in accord with pure foods, and who is not going to create a good feed for animals. That would hurt our business. We want to write to our Senators and tell them to support the revised pure food bill and to give you every assistance.

The CHAIRMAN. I cannot speak for my colleagues, but I will read your brief when it comes in, I assure you.

Mr. Cox. Thank you.

The CHAIRMAN. I will call on Col. J. H. Hayes, of the Chesebrough Manufacturing Co.; of the Stanco Co.; of Daggett & Ramsdell Co.; and others. He represents a great many companies, but we are only going to allow him 5 minutes in which to present his statement, if that is agreeable to him.

Mr. HAYES. That is right.

The CHAIRMAN. Colonel Hayes, proceed.

STATEMENT OF COL J. H. HAYES

Mr. HAYES. The corporations that I represent are in two categories. One that deals with toilet preparations, cosmetics; and the other is a line of drugs. Chesebrough Vaseline, Daggett & Ramsdell and Elizabeth Arden cosmetics; Stanco, manufacturers of Nujol, Misto, and Flit. It was my purpose to analyze the bill to the committee, but I think the bill has been analyzed quite well both by Judge Campbell, and also by Dr. Beal, and other speakers. While we are listed as an opponent to the bill, we are not an opponent to the bill in principle. We are certainly in favor of the protection of the public. We believe that the Department and its officials are earnest in their endeavor to protect the public. We feel that the so-called "fly-by-night" manufacturers should be brought in line; they should be made to obey the law. We feel that no fraudulent or misleading products should be put before the public. The Department, however, can be overzealous and they are seeking perhaps legislation that goes possibly beyond the bounds of reason. I think in this bill here that is presented and that we have been discussing, that they have gone way beyond what is necessary; that have practically told the industry to write a blank check and present it to the Department, for the Department to write in any time whatever amount they feel is needed. We certainly are opposed and object to such a method and such procedure.

Senator McNary spoke about questions of finding of fact and the Department determining that a person is guilty before they send the

case to the district attorney for prosecution. That is exactly the same situation that I got from the bill, and the same opinion that I received of the bill, that you could be tried before the Department and then the facts sent to the district attorney for prosecution and unless the bill is amended in the manner suggested, the defendant would have no chance to controvert or show that the facts were not as they were presented by the Department. This question of discussion has been also with respect to the consensus of opinion. That has been covered quite fully and it is unnecessary for me to make any remarks except that every citizen has his own mind about things, whether they are truthful or not, and in connection with all sorts of conditions. It reminds me very much of a story of an oil producer who went to heaven and applied at the gate and St. Peter came to see him. He asked St. Peter for admittance and St. Peter told him that there were no seats, that the seats were all taken up by prior oil producers, and then the oil producer said, "St. Peter, would you give me a chance to go in there and talk to them?" And St. Peter said, "Yes." And he got in there and in about 10 minutes the whole crowd started to go out of the gate, and St. Peter said to this oil man, "Why are these fellows all coming out?" The saint saw all these men coming out, and this fellow bringing up the rear. He said, "What did you do to bring all of these fellows out?" "Well", said the oil man, "I told them that a million-barrel gusher had just been struck down in hell." "But", said St. Peter, "Why are you going along?". The oil man replied, "Well, St. Peter, there may be some truth in it, so I am going too."

That is the same thing that is going on in the marketing today in this country. I will not take up a great deal of your time with that. We have your permission already to submit a brief covering some of the points that we are interested in, and I will content myself with furnishing that.

The CHAIRMAN. We would be glad to have your brief. I will now call upon Mr. Samuel Fraser, Rochester, N.Y., representing the International Apple Association.

STATEMENT OF SAMUEL FRASER, ROCHESTER, N.Y.

Mr. FRASER. The International Apple Association, and, also, I am specifically representing various cooperative organizations and the other fruit interests in the Pacific Coast States as the Wenatchee Valley Traffic Association, Wenatchee, Wash.; Yakima Valley Traffic and Credit Association, Yakima, Wash.; and we wish to file a special memoranda with the committee later collectively or separately.

The CHAIRMAN. I will be glad to receive it.

Mr. FRASER. Also, I represent the California Fruit Exchange, and the western division of the Chamber of Commerce of the United States, and the latter ask that I file with you a resolution which I submit:

FOOD AND DRUG RESOLUTION

Whereas there is pending before Congress for consideration at the coming regular session Senate bill 1944 and House of Representatives bill 6110, duplicate bills containing proposed radical changes in the present Federal Food and Drugs act; and

Whereas there is no need for the alliance of food and drugs and cosmetics in the same act: Now, therefore, be it

Resolved, That the Chamber of Commerce of the United States of America, western division, protests against the passage of this bill in its present form and urges the Congress of the United States to consider the food industry on its own merits in a separate bill.

This resolution is filed only as expressing the position of the Chamber of Commerce of the United States, western division. I have no authorization to express an opinion on this point for the International Apple Association.

There are certain things that the fruit growers are particularly concerned with. I might say that we very much appreciate Dr. Campbell and Dr. Haven Emerson's statement in regard to the necessity for the tolerances on fruits and vegetables. A very wise legislator and administrator named Moses, 3,500 years ago, told his people that the great problem confronting them in their existence was the control of insects. From that time to this we have had increasing reason to appreciate the force of his statements. He said, "You cannot serve Baal", for Baal was the god of flying things, "If you are going to live, you cannot let him live; you must rid yourselves of him and his, entirely." To attempt to meet the lead tolerance this year many of our industry tried palliative measures; we tried to spray with materials which were suggested and that were new, so that our fruit would be within the tolerances. They failed to control. It cost the fruit growers millions of dollars. The insects destroyed their crops. Dr. Freeman suggested yesterday that there was difficulty in meeting the export standards of tolerances in connection with Maryland apples. I wish to assure you that the tolerances now in force in the United States assure the consumer more protection than is found in any other part of the world. Any apples that can meet the standard of the United States can be exported. The United States is the only country having a tolerance for lead. Dr. Freeman probably misunderstood the conditions as to spray residue in Maryland. The exports are not going because of spray residue holding them up; but because few exports are going out; it is our business relations that are holding them up—tariffs, duties, quotas, and other trade barriers.

Our growers are particularly concerned with certain phases of the bill, and one is section 24. In Great Britain the retailer is held liable if found distributing apples or other fruit showing a spray residue in excess of the tolerance. I do not know from reading this bill, but I would like to know, who would be held liable here—whether the grower, the packer, the wholesaler, or the retailer is to be proceeded against in this county. We believe it would allow us to be victimized if somebody decided that a child had a stomach ache and alleged it was due to spray residue on the apples and it might be only the tannin in the apple or something else, and we ask that this section go out.

The CHAIRMAN. Mr. Fraser, I agree with you fully. I said several times I cannot, for the life of us, see why this was put in the bill. If the injury is received from some food or drug, there is a method provided for it at the present time.

Mr. FRASER. We think it would lead to no end of trouble and we would be in a serious position. We would like, if it is possible, that the word "may" be used in sections 3 and 7 in the first line of each.

The CHAIRMAN. Sections 3 and 7?

Mr. FRASER. That it "may" be deemed to be adulterated, not "shall." If our industry is going under these regulations, I want to

point out that we are under a great many regulations already. None of our packed apples marked under Federal specifications or State mandatory grade laws can be offered for sale unless they meet the grade specifications established for the grade, and, if as laymen, we read this bill, we find that it confers the power on the Secretary of Agriculture, although Dr. Campbell assures me that it will not interfere with current practices in packing, grading, and marketing of apples, it will confer the power to specify the manner in which we must pack and the manner in which we shall mark, and the standards of quality and of fill of package for all fruits and vegetables but, Dr. Campbell has assured me that this matter of standardization of grades, and so forth, will be left with the Bureau of Agriculture Economics, where the handling of this matter now lies. We do not want two bureaus charged with this regulation.

The CHAIRMAN. What is that matter that you are referring to now?

Mr. FRASER. "Section 11. The Secretary is hereby authorized to fix, establish, and promulgate definitions of identity and standards of quality and fill of container for any food."

There are many things with which we have had trouble in the past. We have 48 standards for grades in our different States. We have also definitions of varieties put out by the various Departments of Agriculture, and in our marking requirements for packed apples we now require that even the variety name be marked on the package. We have developed standards of requirements, we have tolerances in regard to spray residue and we had had problems in connection with the fill of the container. At one time we were confronted with regulations possibly prohibiting the use of paper wraps and caps and cushions. The position was taken that these should not be included. My point is that if you give us such phraseology that fresh fruits and vegetables are excluded from the portions of the bill dealing with the provisions covered in Section 11 above and so safeguard our interests, we shall then feel that we are being properly treated in this matter.

The CHAIRMAN. Suppose we were to do that, are there existing laws now that give protection to the public in connection with the sale of fruits and vegetables?

Mr. FRASER. Absolutely. The Federal Government through the Bureau of Agricultural Economics has for years established permissive grades and specifications for apples, pears, and other fruits and a long line of fresh vegetables which grades they keep up to date. These grades together with the State mandatory grades form the basis for the United States Inspection Service for grade and condition. All of the leading apple-producing States, both east and west, have mandatory grade laws or mandatory grades established in conformity with law.

The CHAIRMAN. When you speak about fruits and vegetables, you are speaking of raw fruits and raw vegetables?

Mr. FRASER. Yes. We feel that this matter of grades should be left with the various agencies where it now is. It has taken 20 years of hard work to reach our present position and we are opposed to any disruption.

The question of filling packages is also a very serious problem with us. A proper pack is essential to make a satisfactory delivery. American growers have been packing apples for 200 years for export. They have had experience. If fruits and vegetables go out of these

sections of the bill, of course that will settle the matter; but if we are to be left in, these matters of grade and condition, etc., should remain with the Federal and State agencies where they now rest and where the whole problem of grades and standards has been developed.

The CHAIRMAN. I want to clear up one thing. Is it a fact that these matters of variety and standards of quality and fill are now taken care of by the Department of Agriculture, Bureau of Economics, by laws now in existence?

Mr. FRASER. Yes, and by State mandatory laws and regulations. In this manner and taking the matter of grade: Most States require that the package be branded. If a package is marked with the grade U.S. No. 1, or any other United States grade designation, then it must meet these specifications. Once the container is so marked, it must meet the grade. Penalties apply for misbranding. If apples are sent in bulk or loose in crates, no markings are required although there are canner apple grades covering bulk apples. In addition, there are the State mandatory apple grades in practically all of the leading apple producing States; also mandatory pear and other fruit grades in many of the leading States. If we have to lose all the work we have done and be subject to unknown regulations, the industry I represent views such a situation with alarm.

Next, I want to refer to section 22, "Voluntary Inspection Service." If you intend to develop this service, we would like to ask its use in connection with inspection applying to tolerances in connection with our fruits and vegetables and have any such inspection at point of origin to be final. In other words, we would like to clear our carloads of apples, fruits, and vegetables at point of origin as being within the requirements of the law so far as spray residue is concerned, and not pay out $500 in freight and then find at destination that shipments are held up because someone raises the question of the tolerance.

The CHAIRMAN. Are you proposing that we omit any reference to tolerances so far as apples are concerned?

Mr. FRASER. No. The control of poisons and adulterants should be left where it now is, viz, the Food and Drug Administration.

The CHAIRMAN. I cannot make any promises, of course.

Mr. FRASER. If we have to stay under this law, we want to get all the benefits we can. If we can get the inspection of our cars so that we will know that they are clearly within the requirements of the law, and if we can get certificates which are final which can be attached to the papers that go along with the cars, we would like that very much indeed.

The CHAIRMAN. Have you any precedent for this? Is there anything there in other agricultural provisions?

Mr. FRASER. I do not know of any country where the unqualified and conclusive right is given to clear the commodity at point of origin and have the point of origin inspection absolutely final. The commodity is usually subject to further examination at any time while in transit or on sale.

The CHAIRMAN. What about the grain grading?

Mr. FRASER. I do not know about grain. That is different. You do not have the spray residue and other factors. At the present time, under our Export Control Act for apples and pears, clearances under proper safeguards are being made at point of origin, but it is a privilege extended by the Government and not compulsory on the part

of the Government. On such shipments we have in effect three inspections for we have to meet the tolerance under the Food and Drugs Act in addition to grade and plant quarantine. If all clearances could be secured at point of origin, we would like it.

The CHAIRMAN. What would be the situation as to protest? Would there be any protest?

Mr. FRASER. Under present practice we are subject to reinspection anywhere as to residue, standards of quality, grade, and condition. At present a receiver at any United States destination can call for reinspection or may appeal inspection on all points—grade, condition, etc.

The CHAIRMAN. You would be willing to pay for the inspection?

Mr. FRASER. We are paying for it now. We are maintaining an inspection service available to all the trade, on each car and truck load of fruits and vegetables. Illustrated with apples but practically all fresh fruits and vegetables are being standardized. Shipping-point inspection is growing more and more every year.

The CHAIRMAN. I am more or less unfamiliar with this subject and want to know more of it. Do we have in New York State a Federal inspection such as you have spoken of?

Mr. FRASER. Yes, a combined Federal-State service. We have both shipping-point and destination-receiving-points Federal-State inspection service and the officials issue a Federal-State certificate.

The CHAIRMAN. Is there such an arrangement on the Pacific Coast?

Mr. FRASER. Yes. It is available practically everywhere, either at point of origin or the distributing markets.

The CHAIRMAN. There is a joint inspection so that it can be inspected interstate and intrastate?

Mr. FRASER. Yes, it is all established now. We have a large amount of machinery developed and the Government, the States, and the industry have done a lot of work. I do not think any industry, in cooperation with governmental agencies, has done more to assure the public of a first-class product.

The CHAIRMAN. If this bill were passed as written, would it interfere with what you are doing in your present arrangements?

Mr. FRASER. It certainly would. Under the wording of this bill it would take the establishment of grades away from the States and the Bureau of Agricultural Economics and lodge it in the Bureau of Foods and Drugs. It would disrupt and nullify the principle of State rights as applied to grades. It must be remembered that this is a vast country with varying varieties and conditions and that after all the growers in the respective States have fundamental rights as applied to their grades. Under this bill there is no appeal from whatever blanket all embracing specifications might be laid down by a Federal bureau, which thus far has had no connection or experience with grades.

In the matter of containers, there are now on the Federal statute books four laws relating to standardization of containers for fruits and vegetables:

The standard apple barrel law (also known as the Sulzer bill which was the first bill providing for standardization of a package and for grade specifications, and which was initiated by this industry), approved August 2, 1912. The standard barrel law for fruits and vegetables and the standard barrel for cranberries approved March 4, 1915. The Standard Container Act approved August 31, 1916. The Standard Container Act approved May 21, 1928. The barrel laws and the Container Act of 1928 are weights and measures laws under the Bureau of Standards, and as such apply to intrastate as well as interstate commerce, and to the specifications, marking and fill of the container. These laws apply to barrels, baskets, hampers, climax baskets, etc., and include even the quart and pint tills.

Their development has stimulated the use of the sale of fruits by measure or volume rather than numerical count or weight.

Leading producing States have adopted standardization of container laws and provisions for many commodities they produce.

This bill is destructive of law and the essentials of stability which the law gives, for it authorizes an appointed Executive to prescribe by regulations "the quantity of the contents in such terms of weight, measure, or numerical count as may be prescribed by regulations." All power centers in the Executive. The present bill does not provide for repeal of the present laws so that these would be in effect in intrastate, while regulations of an unknown character would apply in interstate traffic. We could not operate under such conditions. To repeal the present container laws and place this industry under regulations as this bill provides is preposterous and to propose to have both provisions in law will lead to chaos. We cannot conceive how any such proposals should ever have been considered.

Not only that, but under this bill tolerances can be arbitrarily fixed by the Secretary with no right of appeal and no required consultation with the industry. To bring a case and convict and fine, all the Government needs to do is to prove the fixing of the tolerance and by its own analysts that the fruit exceeds the tolerance and the case is ended. The Secretary does not even have to permit the defendant to take a sample of his own fruit and check up on the Government analysis. By section 16 (c) the court may allow a sample to be taken but is not compelled to. The Government does not even have to prove that whatever it finds to be present may be injurious to health. Under the present law and practice, the Government must affirmatively prove its case in each instance including proof that what it alleges to have found is or may be injurious. This is as it should be. The opinions of doctors and toxicologists change and vary from time to time. Every person is justly entitled to his day in court. Under this bill he practically has no day in court. Tolerances can be shifted up or down with very few formalities and to which shifting the citizen is not even required to be consulted.

It is one thing to write in the substance of law provisions which he who runs may read and which are a definite and positive guidance to the courts in the administration of such law, but it is an entirely different thing to invest any person with the right to make law by rules and regulations and subject to constant changes.

A perusal of this bill would lead one to believe that the underlying thought of its purpose is to invest the Secretary of Agriculture with almost complete dictatorial powers and from whose actions and findings there is very little if any appeal.

There are many more features which should be dealt with but I will name but one more and that is the matter of false advertisement as defined in section 9. The wording of this paragraph leaves wide open

the placing of penalties even on the most innocent advertisement. Basing fines and imprisonment on "ambiguities and inferences creating a misleading impression" places the advertiser of fruits and vegetables in a very dangerous position.

We have enough regulations and safeguards for the consumer now. We do not need more.

In grade regulations and their enforcement, the present law, as applied to grades, condition, etc., as now administered by the Bureau of Agricultural Economics jointly with the States, should remain as it now is and fruits and vegetables should be exempted from the definition "food" in sections 3, 6, 7, 9, and 11 by inserting after the word "food", "other than fresh fruits and/or fresh vegetables." Fruits and vegetables should remain in section 10 covering tolerances. This matter belongs to Foods and Drugs Administration, subject to consultation with the industry, a proper right of appeal and subject to the Government proving its case in the event of seizure as I have heretofore indicated.

There is no chance of appeal in this bill that I can find. If we are to meet adjustments proposed by this bill, then you are going to have thousands, yes millions, of dollars lost. We move about a million cars of fruit and vegetables annually by rail and to force such possible far reaching readjustments, with the situation as it now is, would be a momentous undertaking. I am speaking only for the million cars moved by rail; then there is equivalent to a million cars moved by truck. It is a colossal undertaking and a dangerous principle to place such an industry under the arbitrary rule of any executive, no matter how wise he may be, and it is an unwise principle to grant powers on the assumption they will not be used. We are prepared to go along on any reasonable basis, but we are not prepared to disrupt all the progress we have made, to again finance the reestablishment de novo of entirely different methods and practices necessary in the movement of our commodities. We would like to submit a brief and it will take us a few days to prepare that.

(The brief referred to by Mr. Fraser follows:)

Brief of International Apple Association

The proposed Federal Food and Drugs Act, S. 1944, concerns itself with anything which affects the life, structure, and functions of the body of man, or other animals, and all cultivated plants and many not in cultivation. Particular attention must be given to the definitions, for these indicate the scope of this bill.

The manufacture, shipment, sale, advertising, and traffic, in interstate commerce, in any and all things coming within the above scope are by this bill placed under the regulations, and rules to be promulgated by the Secretary of Agriculture, which can be fixed and changed at will. It conveys supreme powers on an appointed executive without, apparently, right of adequate appeal.

The law proposed is not and amendment to the present Food and Drugs Act but is an entire rewriting of the law.

So far as the fruit and vegetable industry is concerned, the disruption which might be forced on the industry by this law may be of so stupendous and far-reaching a character that it might mean the de novo redevelopment of methods and practices in distribution at a cost of untold millions of dollars, the sweeping aside of the practices and laws under which the industry has been developed and now operates and, the possible institution of new methods and practices established, not by law based on economic principles, but by regulations and rules promulgated by an administrative officer of the Government.

We naturally view such sweeping changes with alarm and voice our opposition to the passage of this bill in its present form.

Our interests deal primarily with the food problem. Incident to the production and preparation of food for market, we have an increasing interest in the subject of drugs. In our fertilizers, manures, soil ameliorants, and soil treatments; in the protection of crops against insects and diseases caused by bacteria, fungi, and other agents; in the treatments necessary to prepare our crops for market, their packing, storing, and distribution, we have an ever-increasing recognition of the many ways in which chemistry enters into our life and problems.

This bill, however, goes far beyond this. Not only does it provide for control of standards of quality of food, manner of packing and markings on containers, the containers themselves, supervision of methods of packing, storing, and distribution, but it deals with labels, labeling, advertising, manner of wrapping, and marking in the retail store and provides for unknown regulations and rules, yet to be promulgated, to govern in this vast field.

Present laws, Federal and State, the work and study of generations, the rights of States to their laws, developed to meet specific requirements of a continental range of climatic and other conditions, all these are to be swept aside in order that autocratic powers may prescribe what we can eat and when and how it shall be handled.

If the powers are not to be used, they should not be granted. If granted, they will probably be used and if used, they may so disrupt the industry that great and unnecessary loss will be incurred.

The present law defines food as including "all articles used as food * * * by man or other animals."

In this bill the term "food" as defined in section 2 (*a*) includes everything used for food by man or other animals and all substances entering into their composition. It includes fertilizers for plants and feeding stuffs for animals, the substances from which they are derived and any substance used in their preparation which affects the composition of the crop grown, for example:

In the case of acid phosphate fertilizer, it includes the raw rock from which the fertilizer is prepared and the sulphuric or phosphoric acid used in its acidulation and all the materials entering into the preparation of the sulphuric acid or any other material used in manufacture, for all of these may affect the composition of the crop to which the fertilizer is applied.

In the case of synthetic fertilizers, it covers the air as well as the other ingredients used in their composition.

The proposed act embraces the water used and all fertilizers, manures, lime, land plaster, and other soil ameliorants. Since the bacterial flora and other soil organisms play an important part in determining the nutrient value of the crops grown, cultures of these methods and practices in soil management which increase or reduce their presence and so affect the chemical composition of plants are likewise included.

In endorsing the bill Secretary Wallace referred to the "totally new food constituents and important nutrition elements like the vitamins."

Since the vitamin content of milk is affected by the way in which a cow is fed and the way in which the hay was cured and the manner of light to which the cow has access, these are included. Wide variation exists in the vitamin contents of plants and animals. Boards of health have for years required pasteurizing of milk in specific manner only to find recently that the process ordered and practiced destroyed the vitamins. We are not ready to have standards promulgated in this field for our plants and we cannot too strongly express our disapproval of the proposed manner of placing regulations in effect.

We are not prepared for the possibility of having long established producing sections ruled out of the producing field on account of vitamin content of the roduct or soil, water and climatic conditions resulting in "constituent" content that may not meet temporary theories, or to have rules established as to the use of fertilizer and culture, all to meet an ideal or theoretical concept of what ought to be built into the product by nature. This bill is more far-reaching in its possibilities than many appreciate.

REQUESTED AMENDMENTS

Definitions

Section 2 (*e*)—"Interstate Commerce": The definition as now drawn covers "foreign commerce" as well as "interstate".

Section 2 (*h*) and (*k*): The terms "package" and "in package form" should be clarified. Fresh fruits and vegetables are displayed in their original packages or in bulk. The consumer buys primarily in small quantities by weight, measure,

or units. Obviously a peck or a dozen apples, five pears, a half peck of potatoes, a head of cabbage, or a few onions, carrots, etc., have to be wrapped so that the consumer can get them home. It would be unthinkable as well as a tremendous burden of expense to the consumer, retailer, wholesaler, or producer to require all of these packages or parcels (by whatever designation they may be called) to be labeled as required by section 6 (*b*) and (*c*).

ADULTERATION OF FOOD

Section 3, paragraph (a): Strike out the following: "(2) It it bears or contains any added poisonous or added deleterious substance prohibited or in excess of the limits of tolerance prescribed, by regulations as hereinafter provided."

Substitute therefor the following:

"(2) If it bears or contains any added poisonous or other added deleterious ingredient which may render such article injurious to health."

Reasons.—We are opposed to the arbitrary methods of prohibition and the fixing of tolerances conferred upon the Secretary in section 10, and with no provision for appeal or other legal review of the regulations of the Secretary.

Section 3, paragraph (a) (4), line 6: Strike out the words "may have" and substitute therefore the word "has", so that paragraph (4) will read:

"(4) If it has been prepared, packed, or held under insanitary conditions whereby it has become contaminated with filth,"

Reasons.—Proof not opinion must govern. The commodity has or has not become contaminated. There is a wide difference between "may have" and whether it "has" actually become contaminated.

MISBRANDING—GENERAL

Section 6 (a): Strike out entire paragraph and substitute therefor the following:

"(a) If its labeling is in any particular false or misleading."

Reasons.—The paragraph as it now stands in the bill covers a vague and nebulous field and involves matters incapable of proper proof. Ambiguity, inferences, and impressions have no place in this or any penal statute. They are in the field of psychology. Two different persons may and do in a multitude of instances arrive at different "inferences" and "impressions" from identical statements and words. The apple industry uses terms and other marks provided by law, such as "Extra Fancy," "Fancy," "U.S. No. 1," "Commercial, Utility." These are official designations of grades. It is quite conceivable that to someone they might create a misleading impression. They have meaning to those with understanding of their purpose.

As a matter of fact, "fresh fruits and vegetables" could well be and should be excepted from all of the provisions of section 6 for the reason that the industry is already largely standardized under existing Federal and State specifications, regulations, or laws, covering grades, marks, and the standardization of packages, a violation of which carry penalties.

Section 6, paragraph (b): Insert after the word "form" in line 1 the words "except fresh fruits and vegetables", so that paragraph (b) will read as follows:

"(b) If in package form, except fresh fruits and vegetables, it fails to bear a label containing etc."

Reasons.—1. We have heretofore discussed the method of retailing and the practical impossibility of the retailer labeling every parcel after bulk has been broken and the contents distributed in small quantities.

2. Apparently paragraphs (b) and (c) are intended to apply to manufactured commodities (see regulation 16 under section 8 of the present law), but it is not clear in the proposed bill, since the words "packer, seller, or distributor", might apply to fresh fruits and vegetables as packed at point of production or elsewhere, and also as sold and distributed anywhere in their course from producer to consumer.

3. The fresh fruit and vegetable industry is probably standarized to a greater degree than any other industry, comparable in extent and varieties.

(a) The Bureau of Agricultural Economics has long since set upgrades and specifications for nearly all fruits and vegetables and under which its official inspection service operates or under mandatory State grades, according to the facts.

(*b*) The apples industry has not only the permissive grades and specifications of the Bureau of Agricultural Economics, which became mandatory when one elects to pack and mark thereunder, but in addition all of the leading apple producing States have mandatory laws governing grades, branding, or labeling.

Those laws provide, among other things, for the name and address of the grower or packer, variety, grade, size, etc.

Apple packages in the so-called "barrel States" are in the vast majority of cases not labeled but are stenciled or stamped. In the box States—Pacific coast—they are generally labeled.

These grade specifications, laws, and rules have been developed through a series of years. They should be left where they now are with the Bureau of Agricultural Economics and the States rather than be complicated with the Food and Drugs Administration.

(*c*) *Standardization of packages.*—A standard apple barrel law was passed by Congress, approved August 3, 1912. This was followed by law fixing the standard barrel for fruits and vegetables approved March 4, 1915. These laws specify length of stave, diameter of head, circumference of barrel, and cubic capacity. Following this the Standard Container Act was enacted, approved August 31, 1916. This law prescribes specifications and makes it unlawful to manufacture or sell filled or unfilled, other types. Still later the Standard Container Act of 1928, approved May 21, 1928. This law specifies cubic capacity and makes it unlawful to manufacture or sell other types, filled or unfilled, or to make deceptive packages.

These laws apply to barrels, round bottom, and tub bushel and other sized baskets, hampers, climax and splint baskets of all sizes and tills including quart and pint sizes and provide for their marking as to capacity or volume and penalties if not properly marked when used.

The Barrel Acts and the Container Act of 1928 are weights and measures laws under the Bureau of Standards and apply to intrastate and interstate commerce.

The Container Act of 1928 provides that specifications for any package covered by the law must be submitted to the Department of Agriculture before manufacture. The administration of certification of dimensions essential to comply with the law rests with the Department.

In addition there are many State statutes.

As to the box, the Pacific Coast States, where the box is primarily used, have standardized it by State law and regulations. Other States like Virginia and New York have done likewise.

Standards of fill or the marking of the quantity of contents are also provided in the leading producing States.

4. *Conclusion.*—In view of the foregoing, it is clear that the proposed bill would set up dual, duplicating, and possibly conflicting control over factors already covered. These various standards have been developed through a series of years by both the Federal and State Governments. It is a specialized field in which constant progress has been made. We believe this whole question of standards including grades, marks, and containers should be left with the agencies through which they have been developed, i.e., the Bureau of Agricultural Economics, the Bureau of Standards, and the States.

Nothing is to be gained by covering the same factors in whole or in part in a multiplicity of statutes and administered in whole or in part by different bureaus with the inevitable conflicting and overlapping regulations.

MISBRANDING OF FOOD

Section 7, (a), (b), (c), (d), and (e): We have already discussed in part the extent to which standardization of grade, marks, and packages has proceeded in the fresh fruit and vegetable field and will discuss it further under section 11. Paragraph (a), (1), and (2) are already primarily covered by present standardization laws.

We have no objection, however, to coming under paragraph (a) (1), although it is unnecessary, but do take exceptions to coming under (a) (2) and (d) and (e).

Reasons: 1. Standards of fill in the fresh fruit and vegetable field are already sufficiently established by standard package laws, Federal and State.

2. Definitions of identity, standards of quality, and the question of mandatory labeling as provided in (d) and (e) should not be lodged with the Food and Drugs Administration, since they are already covered by the Bureau of Agricultural Economics and State statutes.

3. As to paragraphs (b) and (c), it is inconceivable, for example, that an apple would be offered as a peach or a pear as a potato or a cabbage, or under any other name than what they are, neither can they or will they be offered as an imitation.

4. Paragraph (f): Fresh fruits and vegetables should be definitely exempted by a proviso after the word "color" in line 8 to read:

"Provided that the foregoing shall not apply to fresh fruits and vegetables in their natural state."

If no definition of identity is prescribed under section 11, then fresh fruits and vegetables would technically come under section 7 (f). Obviously paragraph (f) could not have been intended to apply to fresh fruits and vegetables in their natural state, but it should be made clear:

First: Fresh fruits and vegetables are already identified, not by the Food and Drugs Administration, but by long common usage, such as apples, pears, peaches, prunes, potatoes, cabbages, oranges, etc. Varieties have been and are identified by the American Pomological Society and the United States Bureau of Plant Industry. It should hardly be required that these names be stamped on packages merely because a definition of identity had not been established by regulation by food and drugs.

Second: Also it would be clearly impossible and prohibitive to analyze and label each package of apples, pears, peaches, etc., with the name of each ingredient thereof in order of predominance by weight.

False Advertisement

Sec. 9 (a): Strike out the words: "or by ambiguity or inference creates a misleading impression."

We have already given our reasons therefor. To make persons responsible under highly penal statutes for alleged impressions drawn from alleged ambiguity and inference opens a wide avenue for great injustice.

A person files a complaint and testifies that he had a misleading impression because of ambiguity and inference. Who can disprove it? Who is to decide the question? The Secretary of Agriculture will decide it under sections 15 and 23 (c) and the Secretary's findings under 23 (c) "shall be conclusive."

Basing penal statutes on the varying psychological and mental reactions of 120,000,000 persons is, we submit, exceeding the limits of proper law making.

TOLERANCES, SECTION 10

We have no objection to the fixing of tolerances under proper procedure and safeguards, and subject to review by appeal and to proof in the event of seizures and cases brought that the quantity of alleged poisons found is or may be injurious to health.

Section 10, as now written, goes way beyond the above and way beyond present law. Strictly speaking, the Secretary now has no power to fix tolerances although as a matter of practice tolerances are now promulgated.

As stated above we do not object to the fixing of tolerances, but to the arbitrary and conclusive methods proposed and the absence of safeguards.

What is the Secretary required to do and what is the procedure specified by section 10 and other sections?

1. The section applies both to "constituent" and "added" poisons.

2. The Secretary shall by regulations promulgated "after notice and hearing prohibit such added substances in or on food or cosmetics, or establish tolerances limiting the amount therein or thereon, to such extent as he may deem necessary to prevent such injury to health."

It will be observed—

(*a*) That the character of the "notice and hearing" are not prescribed, nor those who are entitled to be notified, heard, consulted, or considered. In section 11 relating to "Definitions and standards" 30 days' notice of a public hearing is specified. Under the Export Control Act, approved June 10, 1933 (Public, No. 39, 73d Cong.), the Secretary is required to "provide opportunity, by public hearing or otherwise, for interested persons to examine and make recommendation with respect to any standard of export proposed to be established or designated, or regulation prescribed * * *."

Under the proposed wording the Secretary can notify few toxicologists or physicians or health officers or experts on very short notice, hold a limited brief hearing behind closed doors, and announce tolerances that are iron clad, non-appealable, conclusive, and the soundness or unsoundness of which cannot be raised or questioned in any way. We are not reflecting in the slightest upon the merits of toxicologists, physicians, et al.' As everyone knows, however, there are wide differences of opinion on toxicological and medical subjects among the professions themselves and changes in opinion from time to time.

The Secretary should be required to give notice to and hear interested parties including the industries to be affected, otherwise entire industries may be summarily wrecked without opportunity for readjustment or cause tremendous loss and damage.

The fixing of the tolerance for lead on fruit during the past year illustrates the above points. No hearing was held in which the industry participated. The Department in January 1933 had become suddenly very active on lead and as applied to the old crop then in storage, the major portion of which could not be recleaned at that season of the year, due to the lateness of the season, the damage that would be caused the fruit by handling when it was so far along in its life and the heavy expense of unpacking and repacking.

The question then arose in the minds of the industry as to what tolerance would be fixed for the new crop, i.e., the 1933 crop. It became rumored that the Secretary (Food and Drug Administration) might place it as low as 0.014 grains of lead per pound of fruit. The apple and pear industries knew from practical experience that such a tolerance could not be met if insects were to be controlled and a crop of fruit raised.

These industries knew that no efficient substitutes for arsenate of lead had been discovered either by the Government, States, or any other agency. These industries urged with all emphasis possible that anything as low as 0.014 would be impossible and that the matter of fixing a tolerance be delayed until the results of analyses of the old crop could be further completed.

Suddenly out of a clear sky on Sunday April 2 and without a hearing and without a conference with the industry an order was issued by Assistant Secretary of Agriculture R. G. Tugwell, reading in part as follows:

"Beginning with the 1933 shipping season, fruits shipped within the jurisdiction of the Federal Food and Drugs Act containing lead in excess of 0.014 grains lead (Pb) per pound will be subject to seizure and the shippers to prosecution."

The order among other things stated: "This Department and cooperating State agencies are earnestly studying the possibilities of developing effective lead-free spraying materials."

These very same agencies had been studying the very same possibilities ever since 1926 and had found no efficient substitute. It was perfectly well known on Sunday April 2, 1933, that no such substitute existed and, as a practical matter, that none could be discovered and used on the 1933 crop. No efficient substitute has yet been discovered.

The order further recited:

"The lead problem should be avoided entirely wherever possible by the choice of spray materials which do not contain lead."

All of the foregoing resulted in curtailed spray programs and the use of varying substitutes which failed to control insects or which injured the foliage and stunted the fruit. It is impossible to say what all of this cost the growers of the country, but we do know that it ran into very large figures.

Following this and on June 20, Secretary Wallace issued an order raising the tolerance to 0.02 grain of lead per pound. The order recited that the question of substitutes was being investigated, but that a wide survey of producing areas indicated that a spray schedule "adequate to a control of pests will result in an amount of lead residue so great that the most efficient spray removal methods now known will not reduce the lead in a material proportion of the crop to the 0.014 tolerance." This was precisely what the industries involved had pointed out, so far as they were allowed to do so, prior to and after the order of Sunday, April 2. Possibly if there had been a hearing or a conference with the industries, they might have been able to make the facts clearer.

By the time the order of June 20 was issued a material part of the damage had been done. Substitutes which did not control had already been applied in the early stages in many sections or had been purchased. Spray programs are complicated.

They cannot be shifted or changed over night. Supplies have to be purchased in advance. Certain sprays cannot be applied in conjunction with or immediately following others. In brief, plans have to be made in advance.

The order of June 20, which raised the tolerance to 0.02 grains also stated (underscoring ours):

"The tolerance of 0.014 grains per pound will become effective for the 1934 crop *unless the intensive and greatly expanded work now being* carried out on *nonlead arsenicals* proves successful and *permits a total abandonment of lead for 1934.*"

Now let us see how the matter of the discovery of substitutes worked out.

On December 11, 1933, the Department issued an order which, among other things, fixed the tolerance on lead for the 1934 crop at 0.019 grains per pound,

or 0.001 grains less than the order of June 20 covering the 1933 crop. The order, among other things, says underscoring ours):

"*In the absence of a commercially feasible lead arsenate substitute* it is evident that despite the most effective washing method a material amount of fruit will not meet the tolerance of 0.014 grain lead per pound. Accordingly a tolerance of 0.019 grain lead per pound of fruit is announced for the 1934 crop."

Copies of the respective orders are attached hereto.

The foregoing concretely illustrates the wisdom and necessity of hearings or definite consultation with the industries or parties interested.

No matter how good the intent or how high the purpose of administrative officials, and we do not question them in any way but on the contrary pay tribute to their sincerity of purpose, yet no man or men are possessed of infinite wisdom and there are many factors which they cannot know without full consultation.

Fruit growing is an increasing battle with pests, as well as the production of practically all food. If man is to eat, these pests must be controlled.

We in no sense advocate or ever have advocated injury to public health. We think it will be conceded that no industries have ever given a greater, more complete, more earnest, and loyal effort in cooperation with the Government or have brought about a greater readjustment than the apple, pear, and fruit industries.

(*b*) It will further be observed that the fixing of the tolerance by the Secretary is final and from which there is no appeal. Section 10 says that a hearing shall be held, but the type of hearing is not specified, as we have indicated. Section 23 (*c*) prescribes that as to all hearings under the act, "the findings of fact by the Secretary shall be conclusive if in accordance with law."

All that the Secretary needs to do is to fix a tolerance, which is conclusive, make seizures under the act even on suspicion (sec. 16), present an analysis that the commodity seized is in excess of the tolerance, without even being required to give the other party to the seizure a sample, (sec. 16 (*c*)), and the case is complete.

Under the present law the Government is required to prove its case, i.e., that the quantity of adulteration or alleged poison found is or may be injurious to health.

Under the proposed law no such proof is necessary.

The Government should be required to prove its case as at present.

Assume that under the present law that a tolerance was arbitrarily fixed at 0.014 grain per pound. A Government analysis shows 0.015 or 0.016 grain. All the Government needs to do is to prove the two points above and its case is complete. The defendant is not even given the right to have a part of the Government's sample for his own analysis. That is entirely in the discretion of the court (sec. 16 (*c*)).

Furthermore, it is generally recognized and conceded that analyses carried to the third decimal point in terms of grains per pound, or variations of 0.001, 0.002, etc., are in the range of scientific error, depending on various factors, the skill of the analyst, his methods, character of apparatus, purity of chemicals used, etc. Stated in terms of parts per million 0.01 is equivalent to one part in 700,000 and 0.001 is equivalent to one part in 7,000,000.

Analyses cannot be carried to these extreme lengths with any degree of surety. Two different analysts may and actually do arrive at different results on the same sample. Moreover, such minute variations, even if accurate, will not be prejudicial to health in a food like fruit.

Therefore, we again submit that the Government should be required to prove its case and to prove by competent evidence that the amount alleged to be found is or may be injurious to health. The defendant should then be allowed to have his "day in court" and prove, if he can, by competent evidence that the Government's case is not well founded. This is an axiomatic principle of all legal procedure and the rights of citizens.

(*c*) It will be further observed that the proposed bill allows no appeal and no review. The Secretary is constituted a dictator. Court procedure to carry out the dictates of the Secretary are a mere formality with the rights of the defendant foreclosed and prejudged before he gets to court.

Definitions and Standards for Food

Section 11: Insert after the word "food" in line 14 the following: "other than fresh fruits and vegetables".

We have already shown the extent to which standardization of grades, packages, definitions of identity and standards of quality exist in the fresh fruit and vegetable field both under Federal statutes, regulations, and specifications and State laws and regulations.

As we have stated before, these factors should be left where they now are and not complicate and confuse them with dual control and regulation under the Food and Drugs Administration.

Permit Factories

Section 12: This section apparently is intended to apply to manufactured or processed food commodities and not to the packing of fresh fruits and vegetables in their natural state.

We request that it be made clear that fresh fruits and vegetables in their natural state be exempted from the provisions of this section. There is no necessity for such permits in the case of fresh fruits and vegetables.

Investigations and Institution of Proceedings

Section 15 (a): Exemptions and investigations should be limited to officers and employees of the Department of Agriculture and duly constituted health, food, and drugs officers of the respective States, Territories, or political subdivisions thereof. The words "or employee" in lines 15 and 16 should be stricken out. Under the paragraph as it now reads any employee regardless of his knowledge of or connection with health factors could be designated.

Section 15 (a) and (b): These two subdivisions are inconsistent.

Paragraph (*b*) not only authorizes the Secretary to report violations to the United States attorney and to cause appropriate proceedings to be instituted but also gives the same power to health, food, or drugs officers of any State or Territory. Paragraph (*c*) states, however, that the Secretary before reporting any violations to the United States attorney shall "afford due notice and opportunity for hearing to interested parties in accordance with such regulations as the Secretary shall prescribe."

Under paragraph (*b*) it would appear that State or local health, food, or drugs officers could report for the prosecution without affording interested parties either due notice or opportunity for hearing. The principles embodied in paragraph (*c*) should be incorporated in or made applicable to paragraph (*b*).

Seizure

Section 16, paragraph (*c*): This section should be amended to make it mandatory that any party to a condemnation proceeding be allowed to obtain or be furnished with a representative sample of the article seized.

Regulation 3 under the present law specicfially provides that upon request one subdivision of the sample taken by the Government, if available, shall be delivered to the party or parties interested. This regulation clearly recognizes the principles for which we are contending. When the Government takes an ex parte sample and makes an ex parte analysis on which condemnation proceedings are brought and seizures made, the defendant should, as a matter of ordinary justice and for his own protection, be allowed as a matter of right to obtain a representative sample of the article seized.

Section 16 (*e*): This section provides, among other things, that "either party may demand trial by jury of any issue of fact joined in any such case."

So far as we can see under the proposed bill, there is no issue of fact that can be joined as to the merits of the case, and only on the possible question of whether the Secretary has adhered to the procedure of the law and regulations.

Under paragraph (*c*) of section 15, the Secretary in his report to the United States attorney and after hearing accompanies his report by findings. Under section 23 (*c*), all findings of fact by the Secretary in connection with any hearings authorized or required by the act are made conclusive if in accordance with law. There is, therefore, practically nothing for a jury to determine. A jury trial from all practical standpoints would be merely going through the form of ratifying the decisions and findings of the Secretary without any power on the part of the jury to go into the merits of such findings.

This again illustrates the wisdom and necessity of requiring the Government to prove its case as it has to do under the present law.

Penalties

Section 17: This section should be rewritten. The proposed penalties are severe and make no distinction between merely technical violations and deliberate

and fundamental violations. In a large number of instances violations are entirely innocent of any intent, are harmless, involuntary, and excusable. The violation may be only slight. Such violation should be settled by conference and not subject the defendent or the party in error to the harsh penalties proposed in section 17. The proposed penalties should be imposed only in the event of willful and material violators.

Section 17 (a), par. (1): Insert after the word "misbranded" in line 10 the following:

"Provided that no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped, but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this act."

The foregoing is in accordance with the present law.

Imports

Section 20 (a), (1): If section 9 (*a*) is amended to exclude "by ambiguity, or inference creates a misleading impression regarding such food * * *", we have no objection to the prohibition against false advertising on imports, otherwise the same objection applies as to section 9 as it now stands in the proposed bill.

Publicity

Section 21: Strike out the last sentence. Clothing the Secretary with absolute and autocratic power to praise or condemn such commodities as he deems necessary, without a hearing or judicial determination is unwarranted and highly dangerous. In effect, it gives the Secretary the power of life or death over industries and business entirely in his discretion and without recourse.

The Secretary may be mistaken like any other human being. We will remember when the lime-sulphur spray was developing that various official agencies condemned its use as dangerous to the trees and not a proper spray. Later they reversed themselves in the light of experience.

No such vast powers should be lodged in the Secretary, a Government bureau or any other administrative agency. Tremendous and unjustifiable damage could easily be caused thereby. Propaganda has a fertile field in the United States. A few official words published in condemnation of any industry or product would ruin it beyond repair.

If any such power is to be granted, then a provision should be inserted giving the party offended a right of action against the Secretary for damages and directing that any judgment so obtained be paid by the United States Government. Such action should be allowed to be brought in any United States court where the party offended resides. Such right should not be hedged about with technical provisions that would defeat the right and wear out the complainant in attempting to obtain redress.

Voluntary Inspection Service

Section 22: This section should come out or "fresh fruits and vegetables" should be exempted therefrom. It would practically force every grower, packing house, and shipper to go to the expense of maintaining such a service. If one or a few should avail themselves of this section, it would force the hand of the great majority to do likewise in order to compete.

It would be satisfactory to permit such service but without the right to advertise governmental approval. It is one thing to inspect for the purpose of safeguarding health and providing clearance and a sound product before shipment, but quite another thing to be allowed to state that the United States Government is the patron of your product and in effect guarantees it.

If such inspection is set up for the purpose of clearing the product at point of origin, then we would like such inspection to be final without the commodity being subject to reexamination and seizure at point of destination or in consuming markets.

General Administrative Provisions

Section 23 (*a*) and (*c*): Clothing the Secretary with power to make regulations "with the force and effect of law" as in (*a*), with no right of appeal and with no

remedy to test the wisdom, necessity of soundness of such regulations, is to clothe the Secretary with the highest and most extensive autocratic powers.

The same is true of paragraph (*c*) where the Secretary's findings are made conclusive, so long as he has observed the procedure outlined in the bill. This is the most drastic provision that we seem to remember. Other laws give the Secretary the power to make regulations and findings, but many of them go no further than making such findings prima facie evidence.

Under paragraph (*c*) the Secretary is judge and jury, arriving at findings that may be based on facts or alleged facts, limited hearings, opinions, and his own mental processes as to what he may deem necessary. These findings are conclusive. This is the last word in autocracy and depriving a person of his just day in court.

All one has to do is give a casual glance at the hundreds of volumes of cases appealed in Federal and State courts and to see the very large number of cases reversed by the higher courts to be convinced that human judgment is prone to error. It was in recognition of this fact that our judicial procedure was set up and the right of appeal safeguarded.

Under this bill it is apparently and clearly intended to make the Secretary the first, the final, and only authority with the power of life and death over industry within the field to which the bill applies. As highly important as public health is, such extreme measures ought not to be taken in its name.

Liability for Personal Injury

Section 24: This section should be deleted.

Reasons.—The common law covers the rights of a citizen if injured. This provision would stimulate a racket and unnecessary expense for someone. The section does not provide who action is to be against—retailer, wholesaler, packer, or grower, in the case of fruits and vegetables.

Appeals

The bill should either provide the right of injunction against the orders, acts, findings, etc., of the Secretary, or a direct appeal to a Federal court in which event all the issues should be tried de novo. If you want to go that far, make the Secretary's regulations, etc., operative until set aside or modified by the court or make his findings prima facie evidence on appeal. But to cut off appeal and review in toto, except as to mere formalities, violates what has long been regarded as a fundamental legal right and establishes an administrative officer as practically a complete autocrat and dictator.

Samuel Fraser,
Assistant Secretary.

Department of Agriculture,
Office of the Secretary,
Washington, D.C., April 2, 1933.

Notice to Growers and Shippers of Fruits:

The world tolerance of 0.01 grain arsenic trioxide per pound of food will continue in effect during the season of 1933. Experience has shown that with careful adherance to recommended spray programs and the application of appropriate spray residue removal methods this tolerance can be readily met.

Lead is more poisonous than arsenic. Its use under conditions which will leave any residue at time of marketing should be abandoned at the earliest possible moment. This Department and cooperating State agencies are earnestly studying the possibilities of developing effective lead-free spraying materials. Pending the development of such substitutes, protection of the public health demands that lead residues be held to the lowest possible point. Beginning with the 1933 shipping season, fruits shipped within the jurisdiction of the Federal Food and Drugs Act containing lead in excess of 0.014 grain lead (Pb) per pound will be subject to seizure and the shippers to prosecution.

Those who contemplate using lead arsenate on fruit in 1933 should choose cleaning methods which are efficacious in the removal of lead as well as arsenic. The lead problem should be avoided entirely wherever possible by the choice of spray materials which do not contain lead.

In turning to other insecticides the question of their possible effect on health should not be overlooked. The substitution of fluorine compounds for arsenicals

has been urged as a solution of the spray residue problem. There is adequate evidence to establish the deleterious character of certain fluorine compounds and reason to look with suspicion upon all such compounds. The presence of fluorine spray residues on fruits shipped within the jurisdiction of the Federal Food and Drugs Act will be regarded as a basis for action under that law.

Sincerely yours,

R. G. TUGWELL,
Assistant Secretary.

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, D.C., June 20, 1933.

Notice to Growers and Shippers of Fruits:

This Department, in announcing on April 2, 1933, a spray residue tolerance on lead, stated that it, in cooperation with State agencies, was studying the possibilities of developing effective lead-free spraying materials, and that meanwhile lead residues should "be held to the lowest possible point." That announcement fixed as a limit 0.014 grain of lead per pound of fruit.

A wide survey in fruit producing areas has indicated that a schedule of spraying adequate to a control of pests will result in an amount of lead residue so great that the most efficient spray-removal methods now known will not reduce the lead in a material proportion of the crop to the 0.014 tolerance. This tolerance is therefore revised to 0.02 grain lead per pound of fruit for the 1933 crop. The tolerance of 0.014-grain per pound will become effective for the 1934 crop unless the intensive and greatly expanded work now being carried out on nonlead arsenicals proves successful and permits a total abandonment of lead for 1934.

The scope of knowledge of the toxicity of fluorine is restricted. Available scientific data indicate that it is not more toxic than arsenic. Limited experments in the removal of fluorine spray residue point to the conclusion that it is more easily removed than either arsenic or lead. For the 1933 fruit crop prosecutions will not be instituted on fluorine spray residue if the fluorine is not in excess of 0.01-grain per pound.

Very truly yours,

HENRY A. WALLACE,
Secretary.

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, D.C., December 11, 1933.

Notice to Growers and Shippers of Fruits:

In the Department's announcement of June 20, 1933, a lead tolerance of 0.014 was forecast for the 1934 season. In the absence of a commercially feasible lead arsenate substitute it is evident that despite the most effective washing method a material amount of fruit will not meet the tolerance of 0.014 grain lead per pound. Accordingly, a tolerance of 0.019 grain lead per pound of fruit is announced for the 1934 crop. It is hoped that by the end of the 1934 season the various lines of research now under way will enable the industry to meet a tolerance of 0.014 grain per pound the following year and perhaps, to eliminate lead entirely as is now being done in vegetables.

There are no indications of any additional knowledge on the toxicity of fluorine which calls for a change in the tolerance of 0.01 grain per pound announced June 20, 1933. Present indications are that fluorine is not as easily removed as was earlier thought to be the case.

The tolerance for arsenic will remain at 0.01 grain arsenic trioxide per pound of fruit.

Very truly yours,

R. G. TUGWELL, *Acting Secretary.*

The CHAIRMAN. We will be glad to have your brief on the suggested amendment. We will now call upon Dr. George W. Hoover.

STATEMENT OF DR. GEORGE W. HOOVER

Dr. HOOVER. I am a consulting chemist in Washington, D.C. Previously, I was engaged actively in aiding in the enforcement of the Federal Food and Drug Act for some 20 years. The statements that I have to make are not based on theoretical considerations, but are based upon practical experience and with the enforcement of the Food and Drug Act.

Senator MCNARY. Are you for or against the measure?

Dr. HOOVER. I am heartily in accord with the intent and purpose of this bill.

Senator MCNARY. Otherwise you are against it?

Dr. HOOVER. No.

The CHAIRMAN. Go ahead.

Mr. HOOVER. I have an amendment to offer to this bill.

The CHAIRMAN. What page?

Dr. HOOVER. I suggest there be inserted on page 12, section 9, and to be inserted before "False advertisement."

Minor violations. (a) If the Secretary finds food, drugs, or cosmetics in violation of the provisions of this act in minor respects only where no question of public health or fraud and deceit are involved, he shall give the responsible party or parties notice and reasonable opportunity for the correction of such infractions before the application of other provisions of this act.

(b) The Secretary is hereby authorized to make and promulgate regulations for carrying out the provision applying to minor violations of the law.

The CHAIRMAN. You want to make a distinction between minor violations which have nothing to do with public health and more serious ones which may invade the field of public health or perpetrate a fraud upon it?

Senator MCNARY. Will you illustrate the situation?

Dr. HOOVER. In the enforcement of the present Federal Food and Drug Act there arises annually hundreds of cases in which the violations are regarded by officials and all those concerned as inconsequential, insignificant, technical, but they are violations nevertheless. I refer particularly to a case in which there is a declaration of the net contents of the food required to be stated on the label, the regulations require that it be stated in certain sized type, and in certain forms. If found at points where it may not be exactly on the right space or in the same size type, and frequently there is found a poor use of a word or phrase that is wrong, it is not wholly in compliance with the law. These people that make these statements do so honestly and believe that they are complying with the law. The notice to these people in over 95 percent of the cases will cause an immediate correction of the situation. The fact is that this law is being enforced in the present as an absolutely mandatory law. Dr. Wiley held, and succeeding doctors have held, that there is no discretion actually in the law. Consequently, these cases based upon these minor, insignificant, technical violations follow the same course that the violations representing substantial violations, vicious violations of the grossest sort, must go to trial or go through the heavy, cumbersome procedure, and some way should be found to take care of those cases in an efficient and expeditious manner. This is in the interests of the public and the manufacturers alike. If a simple procedure is made to take care of

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these cases you handle 12 of them in the time you can handle 1 case in the heavy procedure. The officials will have time to devote themselves to things that they do not have the time to devote now.

The CHAIRMAN. I am impressed by your suggestion. You will recall yesterday that I asked Mr. Campbell about putting the word "material" in there because it seemed to me that there might be violations unimportant in the sense of their effect on the public health, and I will be very glad if you will give me also a copy of this proposed amendment, and one for the record.

Mr. HOOVER. That represents all I have to say.

The CHAIRMAN. We will call upon at the present time Mr. Donald J. Burke.

Mr. THOMAS. At this time I would like to introduce into the record the National Durg Trade Conference draft of suggested amendments to drug provisions of the present Food and Drug Act, subject to revision, which is to be connected with the statement of Dr. James H. Beal, representing the National Drug Trade Conference. In the following bill each section is designated by the number as given in the code; also by section number of the original act; matter to be deleted is given in brackets; new matter in italic.

In view of the fact that Dr. Beal made certain remarks in the record, I should like to have it included in the record, too, if it can be done.

The CHAIRMAN. In view of your request, it may be included in the record. Just give it to the stenographer and he will take care of that.

A BILL To amend the Food and Drugs Act, June 30, 1906, as amended, August 23, 1912, March 3, 1913, March 4, 1913, July 24, 1919, January 18, 1927, and July 8, 1930, for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, cosmetics, and liquors, and for regulating traffic therein, and for other purposes

8717. SECTION 1. *Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food, drug or cosmetic which is adulterated or misbranded, within the meaning of this act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offence shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment or both such fine and imprisonment, in the discretion of the court.

8718. SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food, drug, or cosmetic which is adulterated or misbranded, within the meaning of this act, is hereby prohibited; and any perons who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such articles so adulterated or misbranded within the meaning of this act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods, [or] drugs or cosmetics, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor and for such offense be fined not exceeding $200 for the first offense, and upon conviction for each subsequent offense not exceeding $300 or be imprisoned not exceeding 1 year, or both, in the discretion of the court: *Provided,* That no article shall be deemed misbranded or adulterated within the provisions of this act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this act.

8719. SEC. 3. That [the Secretary of the Treasury] the Secretary of Agriculture, [and the Secretary of Commerce and Labor] shall make uniform rules and regulations for carrying out the provisions of this act, including the collection and examination of specimens of foods, [and] drugs and cosmetics manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

8720. SEC. 4. That the examination of specimens of foods, [and] drugs and cosmetics shall be made in [the Bureau of Chemistry of the Department of Agriculture] such existing bureau or bureaus in the Department of Agriculture as may be directed by the Secretary of Agriculture, or under the direction and supervision of such bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this act, the Secretary of Agriculture shall cause notice thereof to be given to the [party from whom such sample was obtained] manufacturer of such article if known or if unknown to the party who caused said article to be introduced into interstate commerce. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this act have been violated by such [party] manufacturer or such person who introduced the article in interstate commerce, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

8721. SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

8722. [SEC. 6. That the term "drug", as used in this act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food", as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.]

SEC. 6. The term "food" includes all substances and preparations used for, or entering into the composition of food, drink, confectionery, or condiment for man or other animals. The term "drug" includes (1) all substances and preparations recognized in the United States Pharmacopoeia or National Formulary or supplements thereto; and (2) all substances, preparations, and devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations, other than food, and all devices, intended to affect the structure or any function of the body of man or other animals. The term "cosmetic" includes all substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of, the person.

8723. SEC. 7. That for the purposes of this act an article shall be deemed to be adulterated;

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopoeia or National Formulary or supplements thereto, it differs from the standard of strength, quality, or purity, as determined by the test laid

down in the United States Pharmacopoeia or National Formulary or supplements thereto, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopoeia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopoeia or national Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopoeia or National Formulary: *And provided further*, That no drug defined in the United States Pharmacopoeia or National Formulary or supplements thereto, shall be deemed to be adulterated under this provision if it complies with the standard of strength, quality and purity as determined by the test laid down in the United States Pharmacopoeia or National Formulary or supplements thereto, notwithstanding that it may have been made by a modification of the official formula or directions made necessary to meet manufacturing requirements.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

In the case of confectionery:

If it contain terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consist in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

In the case of cosmetics:

If it contains poisonous or deleterious ingredients in such quantities as likely to be imminently dangerous to the user under the conditions of use prescribed in the labeling thereof, or when used under such conditions of use as are customary or usual.

8724. SEC. 8. That the term "misbranded", as used herein, shall apply to all drugs, or cosmetics, or articles of food, or articles which enter into the composition of food, the package, [or] label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food, [or] drug or cosmetic [product] which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

The term "package" or "original unbroken package" as used herein means the immediate container of the article which is intended to be delivered for consumption by the public. The term "label" includes all written, printed, and graphic matter in any form whatsoever accompanying any food, drug, or cosmetic.

That for the purposes of this Act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis, chloral hydrate, or acetanilid, or barbituric acid, or any derivative or preparation of any such substances contained therein.

Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

Fourth. If it fail to bear the true name and address of the manufacturer, packer, seller, or distributor thereof.

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis, chloral hydrate, acetanilid, or barbituric acid, or any derivative or preparation of any such substances contained therein.

Third. If in package form, the quantity of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count: *Provided, however*, That reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with the provisions of section three of this act.

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided*, That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound", "imitation", or "blend", as the case may be, is plainly stated on the package in which it is offered for sale: *Provided*, That the term "blend" as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further*, That nothing in this Act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except insofar as the provisions of this Act may require to secure freedom from adulteration or misbranding.

Fifth. It it be canned food and falls below the standard of quality, condition, and/or fill of container promulgated by the Secretary of Agriculture for such canned food, and its package or label does not bear a plain and conspicuous statement prescribed by the Secretary of Agriculture indicating that such canned food falls below such standard. For the purposes of this paragraph the words "canned food" mean all food which is in hermetically sealed containers and is sterilized by heat, except meat and meat-food products which are subject to the provisions of the Meat Inspection Act of March 4, 1907, as amended, and except canned milk; the word "class" means and is limited to a generic product for which a standard is to be established and does not mean a grade, variety, or species of a generic product. The Secretary of Agriculture is authorized to determine, establish, and promulgate, from time to time, a reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer; and he is authorized to alter or modify such standard from time to time as, in his judgment, honesty and fair dealing in the interest of the consumer may require. The Secretary of Agriculture is further authorized to prescribe and promulgate from time to time the form of statement which must appear in a plain and conspicuous manner on each package or label of canned food which falls below the standard promulgated by him, and which will indicate that such canned food falls below such standard, and he is authorized to alter or modify such form of statement, from time to time, as in his judgment may be necessary. In promulgating such standards and forms of statements and any alteration or modifi-

cation thereof, the Secretary of Agriculture shall specify the date or dates when such standards shall become effective, or after which such statements shall be used, and shall give public notice not less than ninety days in advance of the date or dates on which such standards shall become effective or such statements shall be used. Nothing in this paragraph shall be construed to authorize the manufacture, sale, shipment, or transportation of adulterate or misbranded foods.

8725. SEC. 9. That no dealer shall be prosecuted under the provisions of this Act when he can establish a guarantee signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, or who caused said articles to be introduced in interstate commerce, to the effect that the same is not adulterated or misbranded within the meaning of this Act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act.

8726. SEC. 10. That any article of food, drug, cosmetic, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, district, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a country foreign, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however,* That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except, that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 10 (a). Notwithstanding the provisions of section 4 the Secretary of Agriculture shall, before certifying any violation of paragraph third "In the case of drugs", in section 8 of this Act, to any United States district attorney to cause criminal proceedings to be commenced and prosecuted or to cause any seizure for confiscation by process of libel for condemnation, cause notice to be given to the person primarily responsible for the representations alleged to be in violation of said paragraph third, and a day to be fixed upon which said person may be heard. No criminal proceeding shall be commenced nor shall any article of drug be proceeded against or seized for condemnation on the grounds that the label or package of said article of drug bears or contains any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein which is false and fraudulent, unless and until the Secretary of Agriculture shall have given the notice and afforded the opportunity for hearing as provided in this section.

At such hearing the party or parties interested may furnish evidence, either by himself or his representative, to justify the representations of therapeutic or curative value made in or upon such label or package.

In the event such person shall refuse or is unable to justify such representations to the satisfaction of the person designated by the Secretary of Agriculture to hold such hearing, the Secretary shall fix a reasonable time for such party to discontinue such representations or to make changes in or upon the label or package in the manner indicated by the Secretary. After such hearing the Secretary shall furnish to such person a statement of his ruling and set forth his reasons therefor.

If such person at such hearing shall by proper evidence justify such representations or shall make changes indicated by the Secretary, the Secretary shall then furnish such person with a certificate that his rulings have been complied with.

In the event of the refusal or failure of such person to conform to directions of the Secretary or his designate within the time so fixed to discontinue representations or make changes in the package or label, the Secretary shall at once certify the facts as provided in section 4 of this Act.

Not more than one action based upon alleged false and fraudulent representations of therapeutic value shall be pending in the courts of the United States at one time until after there has been an adjudication that said article is misbranded within the meaning of said paragraph third herein mentioned.

After notice and upon good cause being shown by the district attorney that an emergency exists, the judge of the court in which said action has been commenced may enjoin the repetitious introduction in interstate commerce of articles similar to the article seized, until such time as the pending cause may be tried.

In the event, after the trial of said single action, there shall have been a final decree or judgment entered in favor of the Government, then further proceedings in libel for confiscation may be commenced against the article of drugs complained of and the label or package bear or contain similar statements, designs or devices and which have been shipped in interstate commerce.

The district attorney may apply to the district court in any jurisdiction where an article of drugs may be found, the label and package of which bears or contains any statement, design or device, concerning the therapeutic value of such article or of the ingredients contained therein which is false and fraudulent, upon a showing that an emergency exists and drastic action in the interests of public health is necessary, and obtain an order directing the United States marshal to impound such article pending further order of the court.

Appeals and other proceedings under this section may be had in accordance with title 12(c), section 1121 (Judicial Code No.129).

.10B. The term advertisement as used herein includes all representations of fact disseminated by the manufacturer, producer, owner or distributor of an article of food, drug, or cosmetic, or by his authorized agent or representative in any manner by other than label, and excludes statements which involve matters of opinion where there is no exact standard of absolute truth. Any advertisement of food, drug, or cosmetic will be deemed false if in any particular representations of fact are untrue. The Secretary shall before reporting any violation of this Act by reason of any advertisement of foods, drugs, or cosmetics for institution of criminal proceedings, afford due notice and opportunity for a hearing to interested parties.

The examination of advertising shall be made in a bureau of the Department of Agriculture as may be directed by the Secretary of Agriculture, and if it appear that such advertisement is false within the meaning of this section the Secretary of Agriculture shall cause notice to be given to the person primarily responsible for the representations appearing in such advertisement alleged to be in violation of this section, and the day fixed upon which said person may be heard. No criminal proceedings shall be commenced on the grounds that said advertisement is false, as defined in this section, until the notice and hearing provided for have been given and afforded. If it appears to the Secretary after such hearing that such advertisement is false as provided herein, then the Secretary shall direct that such party shall cease and desist from making the representations complained of, and in making such order the Secretary shall furnish to such person a statement of his ruling and set forth his reasons therefor. In the event such person shall fail to cease and desist from continuing the representations in such advertising complained of, the Secretary shall at once certify the facts as provided in section 4 of this Act.

.100. The dissemination of any false advertisement as defined in the next preceding section by any means for the purpose of inducing or directly or indirectly the sale of foods, drugs or cosmetics in interstate commerce is prohibited, and any person who violates or causes to be violated any of the provisions of paragraph A of this section, and who shall fail or refuse to comply with the cease and desist order as provided for herein, shall be guilty of a misdemeanor and shall, on conviction thereof be subject to a fine of not less than $100 nor more than $1,000 or imprisonment for not more than one year, or both such fine and imprisonment in the discretion of the court.

8727. SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods [and], drugs and cosmetics which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug or

cosmetic offered to be imported into the United States is adulterated or misbranded within the meaning of this Act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country in which it is made or from which it is exported or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

8727. SEC. 12. That the term "Territory" as used in this act shall include the insular possessions of the United States. The word "person" as used in this Act shall be construed to import both the plural and the singular as the case demands, and shall include corporations, companies, societies, and associations. When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as of the person.

The CHAIRMAN. Now, Mr. Burke, we will hear from you.

STATEMENT OF DONALD J. BURKE, VICE PRESIDENT GEO. H. LEE CO., OF OMAHA, NEBRASKA.

Mr. BURKE. My name is Donald J. Burke, of Omaha, Nebr.

Mr. Chairman, and members of the committee, the experience that I have had includes the practice of law for 5 years before the war, and following the war I taught law for 9 years, and for the last 5 years I have been engaged in the manufacture of drug products which come under the operation of this law. I have had considerable experience during the last 5 years with the operation of the present food and drug law, and with the administration of it.

I have what I think are some constructive suggestions.

In the first place, I feel that there can be no question but what the present law needs to be revised. In 5 minutes I cannot begin to cover such a large subject. I will simply point out the high lights, and a number of points in which the law is clearly defective and must be changed.

The CHAIRMAN. Mr. Burke, I hope, without fail, you will insert in the record the statement you made to me the other day and material which you think you might add, because I think it is very valuable.

Mr. THOMPSON. Is Mr. Burke's proposed draft of substitute bill going into the stenographic record?

The CHAIRMAN. It is already in. He has given it to the stenographer.

Mr. BURKE. I will ask permission to file an exhaustive brief. There is no question about the present law not covering cosmetics, and I think we will all agree that cosmetics must be covered. In the second place, if there is no jurisdiction covering any kind of food or drug advertising at the present time, and I think we all are agreed

that there is none, except perhaps possibly that which is vested in the Federal Trade Commission, or which they have assumed to be vested in them. I am talking about the supervision over advertising in the interest of the consumers or users. There is no question but what the Federal Trade Commission does have jurisdiction of advertising of food or drug products just like all other commodities for the purpose of preventing things which may amount to unfair competition. The Federal Trade Commission does have such jurisdiction. It is very doubtful whether it has any jurisdiction of regulating food and drug advertising in the interest of the consumer. At the present time it is exercising that power, but it is probable that it is exercising it merely by a regulatory extension of its power. If it is, that jurisdiction is not vested in the proper body. The proper body to control this food and drug advertising is the same body which is proper to control the labels of the products, and that is the Food and Drug Administration. They are equipped to do so and they are equipped with the equipment to make the necessary investigations and have done that in the past and they can do that in the future. They are equipped, in other words, to function properly.

In this proposed draft of substitute bill for the Tugwell bill, I have gone into some of these matters.

Mr. TURNER. Is that going to go into the record?

The CHAIRMAN. It will be given to the stenographer when he finishes.

The CHAIRMAN. Professor Burke, apparently the writers of the bill thought, on page 30, line 20, that by using this language the power supposed to be held in the Federal Trade Commission in relation to the food and drug would be transferred or they would be given equally here.

Mr. BURKE. I am heartily in favor of that. I think, by all means, that that should be done. The Federal Trade Commission is not properly equipped to administer such a jurisdiction, as the Food and Drug Administration can do. Therefore, by all means, the present law should be revised as it would be under the pending bill.

The CHAIRMAN. I think it is only fair to say that the Federal Trade Commission has been hampered by lack of appropriations. Perhaps if they had had the money I think they could have done very efficiently what you have in mind. Your thought is, that as long as this is going to be done, with regard to food and drugs, it should be done by this agency.

Mr. BURKE. The change would permit that, and as long as you are going to make it, I think it would be well to put it into such form as would make it practical and desirable.

There is another point which I would like to make which I have not heard here as yet. I think the machinery and procedure for enforcing the present Food and Drugs Act is woefully inefficient, circuitous, extensive to the Government, burdensome to the manufacturers, and generally improper. I think, by all means, if this law is going to be revised, that there should be a proper procedure and a much better procedure than we have at the present time. I think Mr. Campbell will bear me out, that it takes over 2 years to force a label change. There should be some method whereby the proper results could be enforced properly. In that connection, let me bring out another point which I have not heard discussed. I have heard discussions in respect

of criminal intent and fraud and questions of whether the manufacturer was acting fraudulently, but the law could act whether he was or was not. Mr. Campbell, and I think the whole administration, has reiterated time and time again the difficulties of proving criminal intent, or fraud, or knowledge that the statements are false. On the other hand, we hear people say it is wrong to take away that requirement; a distinction should be made. The law should provide two kinds of procedure, one remedial, the other criminal. Under the criminal prosecution by all means criminal intent should be shown, and the Government should have to prove that intent beyond a reasonable doubt. But if the question is whether certain wording on a label should be changed or not, what difference does it make whether there is the presence of intent or whether he is acting fraudulently, or whether he is not? If he is representing his product as a cure for cancer, the Department ought to be able to make him make that change and make it whether his intent is good or bad. Perhaps I will not have time to do anything more than suggest what to my mind is the proper procedure, but I would say it is along the lines that Dr. ——

The CHAIRMAN. Mr. Burke, we want to hear from you.

Mr. BURKE. It is along the line suggested. I am speaking about remedial procedure to effect necessary proper changes in labels and products. That is, I think the law should be so worded—as I will cover in my brief—so that the containers that my company is using is violating the law in any respect, whether it is because of some statement, on some product, or whether it is because the product is worthless or dangerous, or whether it is because of advertising or any other thing, no matter what it is, the fact is that we are violating something. This would operate to provide an opportunity for the administration and the company concerned to go over this subject. This would be in the way of a hearing, but not a formal hearing, it is more in the nature of an informal conference, it is not a hearing, not a trial, but an informal conference, finding a way for us to put our feet under the table with the officials of the Food and Drugs Administration, as we have done a number of times, and we have always settled the matter promptly. That conference would have this result.

(1) Whether we are doing that thing complained of.

(2) If we are doing it, whether it is a violation of the law—and frequently there can be an honest difference of opinion.

(3) If we agree that we are doing it, and that it violates the law, then a written agreement in form satisfactory to the Secretary whereby we agree to immediately cease and desist the improper practice.

The CHAIRMAN. You are suggesting the language for that in any document?

Mr. BURKE. It is contained in this document here.

The CHAIRMAN. Then let that be incorporated in this record. Give it to the stenographer.

(The document referred to is as follows:)

DRAFT OF SUBSTITUTE BILL FOR TUGWELL BILL

A BILL To regulate the manufacture, shipment, sale, labeling, packaging, and advertising of foods, drugs and cosmetics; to establish standards of identity for, and to prevent the adulteration, misbranding, false labeling, and false advertising of foods, drugs, and cosmetics; and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled:

DESIGNATION OF ACT

SECTION 1. This act may be cited as the "Federal Food, Drugs, and Cosmetics Act."

DEFINITIONS

SEC. 2. As used in this act, unless the context indicates otherwise:

(a) The term "food" includes all substances and preparations, other than drugs, designed, advertised or represented in labeling thereof, to be eaten or drunk by man or other animal.

(b) The term "drug" includes (1) all substances and preparations then recognized in the United States Parmacopoeia or National Formulary or supplements thereto; and (2) all substances, preparations, and devices represented in labeling or advertising thereof for use in or on the human or animal body in the cure, mitigation, treatment, or prevention of disease, or to affect the structure of such body or of any part of it.

(c) The term "cosmetic" includes all substances, preparations and devices, other than drugs and foods, represented in labeling or advertising thereof for use in cleansing or caring for the surface, or any part of the surface, of the human body including eyes, ears, nose, mouth, teeth, lips, throat, nails, scalp and hair.

(d) The term "territory" means any territory or possession of the United States.

(e) The term "interstate commerce" means commerce between any state or territory and any place outside thereof, or between points within the same state but through any place outside thereof.

(f) The term "person" includes all individuals, partnerships, corporations and legal, but unincorporated, associations.

(g) The term "Secretary" means the Secretary of Agriculture.

(h) The term "label" means all labels and all statements and representations, whether written, printed, in graphic form or otherwise, (1) upon the immediate container of any food, drug or cosmetic, and (2) all such upon the outside container or wrapper, if any there be, of the retail package of any food, drug or cosmetic.

(i) The term "labeling" includes all labels and all other written, printed, or graphic matter and all advertisements, statements or representations in any form whatsoever, enclosed in, attached to, or designed to accompany, and accompanying, any food, drug or cosmetic.

(j) The term "advertisement" includes all statements and representations made in any written, printed or graphic form or disseminated by radio and reasonably likely to effect, directly or indirectly, the sale of any food, drug or cosmetic.

(k) The term "in package form" includes all forms of wrapping or packing in which the manufacturer, packer, seller, or distributor of a food, drug, or cosmetic has enclosed it in paper or other material for sale.

(l) The term "filler" means any substance or ingredient in any food or drug which is of no substantial value therein and serves no reasonably useful purpose or, if it does serve a useful purpose, is in a proportion unreasonably in excess of what would be sufficient for such purpose or purposes; unless its presence and proportion are declared on the label or its percentage or proportion is included in a declaration thereon of percentages of inert ingredients; but that term does not include harmless flavoring, or coloring substances or perfumes, in reasonable quantity and proportion.

ADULTERATION OF FOOD

SEC. 3. A food shall be deemed to be adulterated:

(a) (1) If it is, or is reasonably likely to be, dangerous to health under conditions of use usual or reasonably to be expected or (2) if it contains any added deleterious substance prohibited, or in excess of the limits of tolerance prescribed, by regulation; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance; or (4) if it is the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (5) if its wrapper or container is reasonably likely to render the food injurious to health under the conditions specified in the first part of this paragraph.

(b) (1) If damage or inferiority has been concealed in any manner; or (2) if it contains any filler.

(c) If it contains a coal tar color not from a batch certified by the Secretary in accordance with regulations.

ADULTERATION OF DRUGS

SEC. 4. A drug shall be deemed to be adulterated:
(a) If it is, or is reasonably likely to be, dangerous to health under the conditions of use and the directions, suggested, recommended or prescribed in the labeling thereof.
(b) If its name is the same as or simulates a name recognized in the United States Pharmacopoeia or National Formulary or in any supplement thereto, official at the time the drug is introduced into interstate commerce or is manufactured, packaged or labeled in the District of Columbia or any territory, or if it purports to be such a drug, and it fails to meet the definitinon, formula, and description set forth therein, or differs from the standard of strength, quality, or purity as determined by the tests or methods of assay set forth therein. No drug shall be deemed to be adulterated under this paragraph if its label bears, in manner and form prescribed by regulation of the Secretary, a statement indicating wherein its strength, quality, and/or purity differ from such standard as determined by tests or methods of assay applicable under this paragraph.
(c) If it contains any filler.
(d) If its wrapper or container is reasonably likely to render the drug injurious to health under the conditions specified in paragraph (a) of this section.

ADULTERATION OF COSMETICS

SEC. 5. A cosmetic shall be deemed to be adulterated:
(a) If it is, or is reasonably likely to be, injurious to the user under the conditions of use and the directions suggested, recommended, or prescribed in the labeling thereof, or under conditions of use usual or reasonably to be expected.

MISBRANDING, GENERAL

SEC. 6. A food, drug, or cosmetic shall be deemed to be misbranded:
(a) If its labeling is in any material respect substantially false or contains any assertion, representation or statement of fact which is reasonably likely to deceive or mislead.
(b) If, in package form, it fails to bear a label containing the name and place of business of the manufacturer, packer, seller, or distributor.
(c) If any word, statement, or other information required on the label to avoid adulteration or misbranding under any provision of this act or regulation of the Secretary is not prominently placed thereon in such manner as to be easily seen and in such terms as to be readily intelligible to purchasers and users.

MISBRANDING FOOD

SEC. 7. A food shall be deemed to be misbranded:
(a) If it is offered for sale under the name of another food.
(b) If it is an imitation of another food, except that no imitation shall be deemed to be misbranded under this paragraph if its label bears the word "imitation" in juxtaposition with, and in type of the same size and prominence as, the name of the imitated food where such name is most prominently stated.
(c) If it is, or is represented to be, a food for which a definition of identity has been prescribed by regulation, and fails to bear on its label the name of the food defined or fails to conform to such definition.
(d) If it is not a food for which a definition of identity has been prescribed by regulation, and its label fails to bear (1) the common or usual name of the food, if any there be, (2), or if the product has no common or usual name, a truthful and reasonably adequate description or designation of the general character, nature, or properties of the food.

MISBRANDING OF DRUGS

SEC. 8. A Drug shall be deemed to be misbranded:
(a) If it is for internal use by man and (1) if the label fails to bear a statement of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein, or (2) if the product is reasonably likely to be habit-forming and fails to bear prominently the statement "Warning, May be habit-forming."
(b) If it contains ethyl alcohol or ethyl ether and its label fails to bear a statement of the quantity or proportion of such substance.

(c) If its labeling fails to contain reasonably complete, clear, and adequate directions for use and, if reasonably necessary to prevent danger to health, precautions to be taken in its use.
(d) If its name is the same as, or simulates, a name recognized in the United States Pharmacopoeia or National Formulary or any supplement thereto official at the time such drug is introduced into interstate commerce or manufactured, packaged, or labeled in the District of Columbia or any territory, and it is not packaged and labeled as prescribed therein.
(e) If it is a drug liable to deterioration, and is not packaged in such form and manner, or if its lablel fails to bear a statement of such precautions, as the Secretary may prescribe by regulation and the Secretary is hereby authorized to designate by regulation, after reasonable notice and public hearing afforded to interested persons, as drugs liable to deterioration within the meaning of this paragraph, such drugs as may be reasonably liable to deterioration, and to prescribe reasonable regulations for the packaging thereof and for statements, on labels thereof, of precautions to be taken to avoid injury.
(f) (1) If it is an imitation of, or represented in its labeling to be, a different drug.

FALSE ADVERTISEMENT

SEC. 9. An advertisement of a food, drug, or cosmetic shall be deemed to be false if it is in any material respect substantially untrue or reasonably likely to deceive or mislead.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND COSMETICS AND CERTIFICATION OF COALTAR COLORS FOR FOOD

SEC. 10. (a) If the presence of an added deleterious substance in a food or cosmetic is or may reasonably be injurious to health when such food or cosmetic is used according to directions or representations in its labeling or in a manner usual or reasonably to be expected, the Secretary may, by regulation after reasonable notice and public hearing afforded to interested parties, prohibit such added substance in such food or cosmetic, or may establish tolerances limiting the amount therein, to such extent as may be reasonably necessary to prevent injury to health.
(b) The Secretary is hereby authorized, after reasonable notice and public hearing afforded to interested parties, to make reasonable regulations for the certification of coaltar colors which are harmless for use in food.

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 11. The Secretary is hereby authorized to establish, upon reasonable notice and public hearing afforded to interested parties, reasonable definitions of identity for any food. Any such definition may be amended or repealed by the Secretary after such notice and hearing. Any such amendment or repeal shall become effective on a date, fixed by the Secretary, not less than ninety days after promulgation thereof.

PRIMA FACIE EVIDENCE OF INTERSTATE SHIPMENT AND OF INTERSTATE DISSEMINATION OF ADVERTISING

SEC. 12. (a) The sale by any merchants of a food, drug, or cosmetic in a State, the District of Columbia, or any territory, not named on its label as the place of business of the manufacturer, packer, seller, or distributor, shall be prima facie evidence of the interstate shipment and interstate sale of such food, drug, or cosmetic by any such manufacturer, packer, seller, or distributor named thereon.
(b) The delivery or dissemination of any advertisement of any food, drug, or cosmetic, in a State, the District of Columbia, or any territory, not named on the label of such food, drug, or cosmetic as the place of business of the manufacturer, packer, seller, or distributor, shall be prima facie evidence of the interstate dissemination of such advertisement by any such manufacturer, packer, seller, or distributor named on the label.
(c) The dissemination of any advertisement of any food, drug, or cosmetic by radio broadcast over any radio broadcast station or plant usually having an effective radius of reception extending beyond the territorial limits of the State, District of Columbia, or territory in which that station is operated, or over a foreign radio broadcast station usually having an effective radius of reception extending into any State or territory of the United States of America, shall be prima facie

evidence of interstate dissemination of such advertisement by any person named on the label of such food, drug, or cosmetic as manufacturer, packer, seller, or distributor.

FILING RECORDS OF INTERSTATE DISSEMINATION OF ADVERTISEMENTS BY RADIO BROADCAST

SEC. 13. Any manufacturer, packer, seller, or distributor of any food, drug, or cosmetic or other person, who causes the interstate dissemination, or dissemination within the District of Columbia or any territory of any advertisement of any food, drug, or cosmetic by radio broadcast, shall file with the Secretary, unless some other person responsible for the dissemination has so filed, a true and complete copy of the radio broadcast continuity of such advertisement, which shall be a complete and exact written, printed or typewritten record of the advertising statement so disseminated and shall state the date when, and station over which, it was broadcast and shall be verified by the oath or affirmation of the manager, director, or other responsible official or agent of the radio station or plant over which the advertisement was disseminated, within such time and in such manner and form as, the Secretary may by regulation reasonably prescribe; provided that if it shall be impossible or impractical to obtain the verification above provided for, it shall be sufficient that the copy or record be so verified by the oath or affirmation of the person filing the same or of any other person with knowledge of its correctness.

ACTS PROHIBITED

SEC. 14. It shall be unlawful and in violation of this Act—

(1) For any manufacturer, packer, seller, or distributor thereof to introduce into interstate commerce, in the District of Columbia or in any territory, any misbranded or adulterated food, drug, or cosmetic.

(2) For any manufacturer, packer, seller, or distributor of any food, drug, or cosmetic to disseminate any false advertisement thereof by radio broadcast, United States mails, or in interstate commerce, or within the District of Columbia or any territory.

(3) For any manufacturer, packer, seller or distributor of any food, drug, or cosmetic to disseminate within any State of the United States of America any false advertisement thereof reasonably likely to effect directly or indirectly the sale thereof in interstate commerce.

(4) For any person to manufacture any adulterated food, drug, or cosmetic, or to misbrand or adulterate any food, drug, or cosmetic, within the District of Columbia or any territory.

ENFORCEMENT

SEC. 15. (a) The Secretary is charged with the enforcement of this Act and is empowered to enforce it as herein provided.

(b) When the Secretary has reason to believe, and does believe, that any manufacturer, packer, seller, or distributor thereof has misbranded, adulterated, or falsely advertised any food, drug, or cosmetic in the District of Columbia or any territory or has manufactured any adulterated food, drug, or cosmetic therein, or has shipped or sold in interstate commerce any misbranded or adulterated food, drug, or cosmetic, or has disseminated in interstate commerce any false advertisement of any food, drug, or cosmetic, or has disseminated in any State of the United States any false advertisement reasonably likely to affect, directly or indirectly, interstate sales of any food, drug, or cosmetic, or has violated this act in any other respect, and that unless restrained such person will repeat and/or continue such manufacture, misbranding, adulteration, false advertising, or other violation or violations of this act, the secretary shall give such persons reasonable notice, according to regulation, to appear at a time and place certain, either within the District of Columbia or within the State or territory where the person resides or has his principal place of business, for an informal conference regarding such believed unlawful acts or practices and for the purpose of coming, if possible, to an agreement with him whether such acts or practices have been committed by such person, whether they are in violation of law, and, if so, for the prompt and voluntary discontinuance thereof by such person; such notice shall describe the believed unlawful acts or practices in a general way and sufficiently for such person to understand the things to be discussed and considered at the conference.

(c) If the person so notified appears in person or by attorney or other authorized representative such conference shall be conducted by the Secretary in an informal and bona fide effort to effect a proper agreement regarding the facts and the law applicable thereto and, if this Act is then believed by the Secretary to have been violated by such person, to induce such person voluntarily to refrain from all such unlawful acts and practices and to enter into a written agreement with, and in manner and form satisfactory to, the Secretary so to do.

(d) If the person does sign such agreement in form satisfactory to the Secretary and as long as he fully and fairly complies with it, he shall not be cited to show cause why a cease-and-desist order commanding him to refrain from any such acts or practices should not be issued.

(e) But if such person fails to appear for such informal conference, or if he does appear but refuses to sign such an agreement or if after signing such agreement he fails to comply substantially with it, the Secretary shall give him reasonable notice, served personally or by registered mail and as shall be provided for by regulation, to appear at a time and place certain, either within the State where such person resides or has his principal place of business or in the District of Columbia, and show cause why a cease-and-desist order shall not be issued by the Secretary commanding him to refrain from the believed violations or violations of this Act, which believed violation or violations shall be described with reasonable particularity in such notice.

(f) At the time and place specified in the notice and/or at such other times, and at such other places as specified in the preceding paragraph of this section, to which the hearing thereon may be continued by the Secretary, such person so cited, hereinafter referred to as the respondent, may appear in person or by attorney or other authorized representative, and the hearing regarding the believed or alleged act or acts of respondent described in the notice, and upon such answer in writing as respondent has filed, or may then file, with the Secretary or upon his verbal answer, shall be conducted by the Secretary.

(g) The hearing shall be conducted in an orderly but expeditious manner, and the Secretary shall hear witnesses, sworn or upon affirmation, for the Government and for respondent, if any, and shall consider their testimony and any documentary and real evidence and written or oral arguments that may be offered in behalf of the Government or respondent. If respondent does not appear and show cause the Secretary shall conduct such hearing, as may be proper and sufficient, without him.

(h) At the conclusion of the hearing, if the Secretary finds that respondent is not guilty of any act, conduct, or practice described in the notice or that the acts so described do not constitute a violation or violations of this Act, he shall make his findings of fact and of law in writing and shall enter an appropriate order thereon vacating the notice to show cause.

(i) If, at the conclusion of the hearing, the Secretary finds that respondent is guilty of any act or acts described in the notice and that such act or acts constitute a violation or violations of this Act, he shall make his findings of fact and of law in writing and shall enter thereon a cease and desist order commanding respondent, and his officers, agents, employees and representatives for him, to refrain from the violation or violations so found and shall cause a duly certified copy of such cease and desist order to be served upon respondent personally or by registered mail and as prescribed by regulation; provided that, unless the notice to show cause was issued because of violation by respondent of a written agreement as provided for in paragraph (c) of this section, the Secretary may stay the proceeding until further notice, upon the signing by respondent of such an agreement in manner and form satisfactory to the Secretary, and the proceeding shall thereupon be stayed as long as respondent substantially complies with the agreement and until the Secretary, by appropriate order, may vacate the notice to show cause or may, if he has reason to believe respondent has violated the agreement, set a time and place certain for the further hearing on said notice to show cause and gives respondent notice thereof as provided in paragraph (e) of this section; if such notice to reappear is given the proceeding shall be resumed according to the terms of the notice.

(j) The testimony in the hearing shall be reduced to writing or reporter's notes and it and all documentary and real evidence in the hearing shall be preserved by the Secretary until such time that an appeal from the order cannot be taken, or longer as the Secretary deems expedient, or until the transcript of the evidence is, in case of appeal, transmitted to the appeal court. And the Secretary shall keep a permanent record of the proceeding, hearing and orders. Until time for appeal from any order has expired or until such appeal is taken, as hereinafter provided, the Secretary may, by order upon motion of respondent, or upon reasonable notice to respondent as provided for in paragraph (e) of this section, modify or set aside, in whole or in part and as he deems proper, any ruling, finding

or order in the proceeding; but, a duly certified copy of such order shall be served on respondent in the manner provided for in paragraph (i) of this section, and upon modification of any cease and desist order the time for appeal therefrom shall continue for thirty days from the serving upon respondent of the certified copy of such modified order.

(k) If respondent does not appeal from a cease and desist order within the time as hereinafter provided, such order shall become final and shall be by the Secretary published; but no information regarding suspected or believed violations of this Act, or regarding conferences or notices to show cause or of any of the proceedings, provided for in this section, shall be published with identifying reference to the respondent or any person believed guilty thereof, by the Secretary or any other official or employee of the United States of America before a cease and desist order in such proceeding shall have been entered and shall have become final, except such publications as may be reasonably necessary to prevent or warn against the consumption or use of adulterated food, drugs, or cosmetics imminently dangerous to health; provided this paragraph shall not be held to prohibit confidential communications to other officers, agents, or employees of the Government in performance of legal duty.

(l) The respondent may obtain a review of the cease and desist order, and of the whole proceeding, in the Circuit Court of Appeals of the United States for the circuit in which he resides or has his principal place of business, by filing, within 30 days after the service upon respondent of the duly certified copy of said order, in the court a written petition identifying the Secretary's order and praying that it be set aside. A copy of such petition shall be served forthwith upon the Secretary personally or upon some official by him designated and as prescribed by regulation or as may be ordered by any judge of said court and thereupon the Secretary forthwith shall certify and file in the court a transcript of the entire record in the proceeding, including all the testimony taken and all documentary and real evidence, and of his findings and orders therein.

(m) After such notice of appeal has been so served, said cease and desist order shall not become final unless and/or until it may be affirmed by said court, and said court shall have exclusive jurisdiction in the proceeding and of all questions of fact and of law involved in the notice or notices, findings and orders or orders. The court may/shall in its discretion take additional evidence or may enter its decree upon the record, transcript, pleadings, and arguments and briefs of counsel, and the findings of the Secretary as to the facts shall be regarded by the court as prima facie. The court shall have power to enter, upon the record, testimony and proceedings, below and upon the pleadings and testimony if any adduced before it, a decree affirming, modifying, or setting aside any order or orders of the Secretary or any such written agreement as hereinbefore provided for, in the proceedings, and the court may, as the Secretary could have done, accept such an agreement in the name of the Secretary. If the court affirms the cease and desist order as made by the Secretary or as modified by the court, such order as affirmed shall be final and in all respects equivalent to a final cease and desist order of the Secretary, and it shall also be the order and mandatory injunction of the court and, as such, shall be enforcible by contempt proceeding. If the court sets aside the cease and desist order without entering a different one or otherwise disposing of the action or continuing it, it shall dismiss respondent without delay. The court may, in its discretion, continue the action, exercise the same discretion or enter any order as the Secretary could properly do while the proceeding was before him. The final disposition of the case by the court shall be published by the Secretary as final cease and desist orders are by him published. The decree of the court affirming or setting aside the cease and desist order or entering a different one shall be final, except that it shall be subject to review by the Supreme Court upon certiorari.

(n) Original jurisdiction to institute and conduct proceedings for and to issue cease-and-desist orders to prevent violations of this Act is vested in the Secretary as herein provided and exclusively.

SEIZURES OF MISBRANDED OR ADULTERATED FOOD, DRUGS, OR COSMETICS

SEC. 16. Any food, drug, or cosmetic so misbranded or adulterated within the meaning of this Act, or so handled by any carrier or carriers of communicable disease, or handled, processed, or packed under such conditions as to be imminently dangerous to health shall be liable to be proceeded against while in interstate commerce or at any time thereafter and at all times in the District of Columbia or any Territory, by a process of libel for condemnation in any district

court of the United States within the jurisdiction of which the article is found, and the fact of imminent danger to health by reason of adulteration and/or misbranding and/or such handling, processing, or packing is cause for condemnation by order of the court. If any food, drug, or cosmetic is so condemned as being adulterated, within the meaning of this Act, and imminently dangerous to health, the same shall be disposed of by destruction as the court may direct. Any food, drug, or cosmetic condemned as being so misbranded and/or so handled, processed, or packed, but not adulterated, shall be disposed of by destruction or sale, the court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such food, drug, or cosmetic shall not be sold in any jurisdiction contrary to the provisions of this Act or to the laws of that jurisdiction or in violation of any reasonable condition fixed by the court; and upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act or of the laws of any State, Territory, or of the District of Columbia or in violation of any reasonable condition fixed by the court, by the owner of such condemned merchandise which would not be imminently dangerous to health if properly labeled and/or conditioned, the court shall by order direct that such merchandise be delivered to the owner thereof. The proceedings in such libel cases shall conform, as near as may be, to the proceeding in admiralty, except that either party may demand trial by jury of any issue of fact joined in such case, and all such proceedings shall be at the suit of and in the name of the United States and shall be instituted immediately by the United States District Attorney of the district in which such food, drug, or cosmetic is located, when requested to do so and furnished with necessary information by the Secretary. If it is found that the merchandise so seized is not adulterated or misbranded or, if adulterated and/or misbranded, is not by reason thereof or by reason of any handling, processing, or packing imminently dangerous to health, the court shall dismiss the action and, by proper order, restore the merchandise to the owner or other proper person.

GENERAL ADMINISTRATIVE PROVISIONS

SEC. 17. (a) All of the powers herein conferred upon the Secretary may be exercised by him personally or by such officer or officers, employee or employees as, and to such extent as, the Secretary may designate.

(b) The Secretary is authorized to prescribe such regulations as may be necessary or reasonable for the efficient enforcement of the functions vested in him by this Act, and wherever, in this Act, reference is made to any regulation or regulations, reasonable regulation prescribed and promulgated by the Secretary is intended unless the context indicates otherwise and except as provided in paragraph (c) of this section.

(c) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe such regulations as may be necessary or reasonable for the efficient enforcement of the provisions of section 18 of this act.

(d) All regulations of the Secretary, or of those Secretaries authorized by this Act shall be of general application and shall take effect only after public promulgation in such manner as the Secretary or, in case of joint regulations, those Secretaries shall reasonably specify, and all regulations herein authorized shall be by the Secretary published and available to any interested person upon request.

(e) It shall be the duty of each district attorney to whom the Secretary of Agriculture shall present satisfactory evidence of any criminal violation of his Act, to cause appropriate proceeding to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

(f) Except as permitted in paragraph (k) of section 15 it shall be unlawful for the Secretary or other officer or employee of the United States to publish information of any believed or suspected violation of the provisions of this Act regarding adulteration, misbranding, and/or false advertising of food, drugs, and/or cosmetics, with identifying reference to the believed or suspected violator or guilty person, except confidentially to other officers, agents or employees of any department or branch of the Government and in the performance of his and their duty, before a cease and desist order based on it or on them shall have been entered and shall have become final and except as provided in paragraph (m) of section 15 of this Act.

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IMPORTS

SEC. 18. (a) The Secretary of the Treasury shall deliver to the Secretary of Agriculture upon his request, from time to time, samples of food, drugs, and cosmetics which are being imported or offered for import into the United States, giving reasonable notice thereof, by personable service or registered mail and as prescribed by regulation, to the owner or consignee who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that any articles, packages, or lots of such food, drug, or cosmetic is adulterated or misbranded within the meaning of this Act, such articles, packages, or lots shall be refused admission.

(b) The Secretary of the Treasury shall refuse to deliver to the consignee, and shall cause the destruction of, any food, drug, or cosmetic so refused admission, unless the same is exported by the consignee or, with the permission of either or both of said Secretaries, is changed so as to be no longer adulterated or misbranded, within three months from the date of notice of such refusal under such regulations as the Secretary of Agriculture and the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon, and on refusal to return such article or any part thereof for any cause to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose said consignee shall forfeit the full amount of the bond as liquidated damages.

(c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

DEFINITIONS OF CRIMINAL VIOLATIONS

SEC. 19. The following acts are hereby prohibited and declared criminal:

(1) The intentional introduction into interstate commerce of any adulterated or misbranded food, drug, or cosmetic by any manufacturer, packer, seller, or distributor thereof with knowledge or adequate reason to believe that said food, drug, or cosmetic is adulterated or misbranded.

(2) The intentional dissemination of any false and fraudulent advertisement by radio broadcast, United States mails, or in interstate commerce for the purpose of inducing or effecting, directly or indirectly, the purchase of any food, drug, or cosmetic, by any manufacturer, packer, seller or distributor thereof with knowledge or adequate reason to believe that said advertisement is false.

(3) The intentional dissemination of any false and fraudulent advertisement by any means for the purpose of inducing or effecting, directly or indirectly, the sale of any food, drug. or cosmetic in interstate commerce, by any manufacturer, packer, seller, or distributor thereof with knowledge or adequate reason to believe that said advertisement is false.

(4) The fraudulent manufacture of any adulterated food, drug, or cosmetic, or the fraudulent misbranding, adulteration, or false advertising, of any food, drug, or cosmetic by any manufacturer, packer, seller, or distributor thereof, in the District of Columbia or in any territory.

(5) The intentional or criminally negligent failure to file, by any person charged to file, with the Secretary, within such time and in such manner and form as the Secretary may by regulation specify, a true and correct record of any radio broadcast advertisement as provided for by section 13 of this act.

(6) The publication by any officer, agent or employee of the United States of any charged or suspected violation of this Act, or of any information regarding any suspected or believed violation thereof or regarding any conference or notice to show cause or of any proceeding or hearing, provided for in section 15 of this act, in connection with any identifying references or reference to the person or persons involved, except such publications as may be reasonably necessary to prevent or warn against the consumption or use of adulterated food, drugs or cosmetics imminently dangerous to health, and except such publications regarding acts or practices that shall have been specifically forbidden by cease and desist order or orders that have become, and then are, final and in effect, and except publication of such cease and desist orders and of the final disposition of cases by courts as provided for in paragraphs (k) and (m) of section 15 of this Act, and other than confidential communications to other Government officers, agents, or employees in the performance of official duty.

(7) The intentional violation of any cease and desist order authorized in this Act, after it has become, and while it is, final and in effect, by any person ordered thereby to cease and desist or by any officer, agent, employee, or representative of such person.

PENALTIES

SEC. 20. Any person who knowingly and willfully violates, or causes to be violated, any provision of section 19 of this Act shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or to a fine of not more than $1,000, or to both such imprisonment and fine, in the discretion of the court.

EFFECTIVE DATE AND REPEALS

SEC. 21. (a) This Act shall take effect six months after the date of approval. The Federal Food, and Drugs Act of June 30, 1906, as amended, (U. S. C., title 21, sections 1 to 15) shall remain in force until such effective date, and is hereby repealed effective upon such date: *Provided*, That upon the approval of this Act and before its effective date the Secretary is authorized to conduct hearings for, and to promulgate, regulations, definitions and standards, under the provisions hereof, which regulations, definitions, and standards shall become effective on or after the effective date of this Act as the Secretary shall direct.

(*b*) The provisions of this Act shall not be held to modify or repeal, but shall be held in addition to, the prvisoions of the following Acts, as amended: The Tea Import Act, approved March 2, 1897 (U.S.C., title 21, sections 41–50); the Virus Act, approved March 4, 1913 (U.S.C., title 21, sections 151–158); the United States Grain Standards Act, approved August 11, 1916 (U.S.C., title 7, sections 70–87); the Insecticide Act, approved April 26, 1910 (U.S.C., title 7, sections 121–134); the Import Milk Act, approved February 13, 1927 (U.S.C., title 21, sections 141–149); the Caustic Poison Act, approved March 4, 1927 (U.S.C., title 15, sections 401–411); the Virus, Serum, Toxin and Antitoxin Act, approved July 1, 1902 (U.S.C., title 42, sections 141–148).

(*c*) All other Acts inconsistent with this Act, and all other parts of Acts inconsistent with this Act, are hereby repealed.

The CHAIRMAN. Will you proceed.

Mr. BURKE. I think Mr. Campbell will agree that would take care of 95 percent of the cases now. It would take care of all the cases except where the manufacturer is acting in bad faith or where he is stubborn and where he is trying to defraud, which would not be more than 5 percent and maybe 15 percent of the cases in which there was a bona fide difference of opinion.

Under the present procedure it requires the enforcement to start by the seizure actions. Mr. Campbell and his subordinates will not make a seizure against any company unless they are satisfied that they can go into court and back up their seizure. (To Mr. Campbell:) Is that not a correct statement?

Mr. CAMPBELL. If there is a violation and we know it, of course we enforce the law.

Mr. BURKE. But you first prepare your data and see that you are satisfied?

Mr. CAMPBELL. We always undertake to make an administrative determination of the facts first.

Mr. BURKE. The point I am making is this, that it takes time and if you can have some way by which you can go into an informal conference where there is no danger of a commitment by anyone, you will be able to proceed much more rapidly and in 75 percent of these cases where now months must elapse, you would be able to settle the matter in a month. This would all be done away with by having a new enforcement machinery such as I suggest.

The CHAIRMAN. Can you put that in your brief in greater particularity? That is, in addition to the document which is over there?

Mr. BURKE. I can finish it in a minute.

The CHAIRMAN. Proceed.

Mr. BURKE. If we fail to bring about such a conference, or having brought about such a conference we fail to enter into any agreement, or, if having entered into an agreement we fail to abide by it, why then the administrator would serve on us a summons to bring us into court and to show cause why we should not have a cease and desist order run against us so that we would be punishable for contempt of it. Of course, we would have to have a right of appeal. Once that cease and desist order would become official, then we would have to have the right of appeal of our cause to the court permitted under the act.

(The brief and analysis subsequently submitted by Mr. Burke follow:)

BRIEF, SUPPLEMENT, AND ANALYSIS FILED BY DONALD J. BURKE, VICE PRESIDENT OF GEO. H. LEE CO., OMAHA, NEBR.

I feel qualified to address you regarding the existing Federal Food and Drugs Act and regarding the pending bill for its revision, because of the following facts. I am by training a lawyer and spent 5 years in the general practice of law before the war. For 9 years following the war I was a full-time professor of law on the faculty of the Creighton University School of Law in my home city, Omaha. I am Executive vice president of the Geo. H. Lee Co. and have held this position for nearly 6 years. We manufacture poultry medicines, products that come under the existing Food and Drugs Act. During those 6 years I have had occasion a number of times to come to Washington and to discuss problems under that law with officials of the Food and Drug Administration of the United States Department of Agriculture. I am acquainted with a number of the officials who administer that law and have had considerable experience with its workings. I have also had experience with the work of the Federal Trade Commission in its supervision over the collateral advertising of products that come under the existing law.

Because of my training in the law and of my experience in the manufacture and advertising of products that are within the operation of the existing law, and because for several months and ever since the pending bill was introduced, I have given it very close thought and study, I feel that I am in an exceptionally good position to correctly estimate the deficiencies of the present law and the legal and practical effects the pending bill would have if enacted—much better than the ordinary lawyer who did not have my experience in the manufacture and advertising ofproducts within the operation of the existing law or my intimate experience with its workings and of the difficulties in its administration, and better than that of manufacturers and of officials who have not had my legal training.

From my training and experience and from my careful study of the pending bill I feel strongly that its enactment would be actually destructive of a big, legitimate industry, the prepared medicine industry, that it would be extremely injurious to the entire drug industry and to the food and cosmetic industries, that it would throw many thousands of men and women out of useful employment, would seriously retard economic recovery and that, in its very scheme and essential provisions, it is devastatingly inimical to the whole spirit of the N.R.A. It is composed of provisions that are arbitrary, bureaucratic, and destructive. And unnecessarily so; all the good things designed to be accomplished by the pending bill could be effected by one free from those unwise, unjust, and un-American provisions. No one could possibly be more sincerely or more strongly opposed to the arbitrary and bureaucratic and destructive features of the pending bill than I. I have worked hard to defeat such legislation and I will continue to fight it.

On the other hand, I am warmly sympathetic with all bona fide efforts to rewrite the existing law in a constructive way. I am convinced that the existing law is woefully inadequate and needs constructive revision or rewriting in the interests of the people, in the interests of the officials charged with its administration, and to bring about a better administration, and even for the protection of manufacturers and advertisers of products within the operation of the law.

It is not true that the present law is adequate. No right-minded and impartial person to whom its defects are pointed out can fail to understand that it is seriously defective. The act of 1906 was wonderfully constructive legislation and has done an immense amount of good. But there are seven respects in which that law should be improved. Permit me to point them out.

1. The present law does not cover cosmetics or physical appliances that are depended upon by the sick, such as braces, trusses, ultra-violet ray and infra-red ray lamps. Everyone knows that people can be injured by cosmetics and by such appliances and that false claims can be made for them that hold out false hopes to the suffering who frequently neglect proper treatment because of them. I can't appreciate how any right-thinking person can question the importance of bringing cosmetics, and physical appliances for which curative claims are made, under the law. But there is absolutely no regulation or control over such products. This statement demonstrates that the present law is inadequate in this respect and should be changed.

2. The worst abuses in the advertising of food and drugs occur over the air but, under the present law, cannot be stopped or controlled. There is just as much reason why food, drug, and cosmetic advertising by radio should be bridled, as there is for controlling such advertising when printed. But there can be no question about it: There is absolutely no control over advertising claims and representations made over the air. There can be presented no possible argument why advertising claims and representations for food, drug, or cosmetic products should not be under the same regulation and control when made over the air as when printed. Therefore the present law is patently defective in this respect and needs to be changed.

3. If there really is any jurisdiction over any kind of food and drug advertising (not labels or labeling) in the interest of consumers and users and not simply for the protection of competitors against practices amounting to unfair competition. it is only such as may possibly be vested in the Federal Trade Commission. As a lawyer I question very seriously whether there really is any jurisdiction or lawful supervision over collateral advertising of such products. But if there is any jurisdiction in that field it is only such as may possibly be vested in the Federal Trade Commission. And that Commission is not the logical body, and is not equipped, to exercise it efficaciously. The properties and efficaciousness of such products, and the validity of scientific claims made for them, must be passed upon by the Food and Drug Administration in respect of their respective labels and labeling. The same Governmental agency that determines those questions and applies the law in respect of labels should exercise the same control regarding collateral advertising of such products. The Food and Drug Administration should have authority to prevent abuses in the advertising of food, drugs, and cosmetics, whether printed or by radio. In this respect the present law is clearly inadequate and should certainly be changed.

4. This fourth point cannot be made so clear to a person who has not had personal experience with the enforcement of the existing law. But it is just as real and serious a defect as the others. It is this. The present law does not provide sufficiently direct and simple procedure for stopping violations of the law. The officials are obliged to resort to the circuitous, clumsy, expensive, and damaging procedure of trying to harass manufacturers into making required changes; they do this by bringing seizure actions and destroying dealers' stocks of the product until finally the manufacturer, worn out by injury caused indirectly to his business, yields.

This is the way it works. If officials of the Food and Drug Administration believe that improper claims are made upon the label of a drug product, their first action is to bring a seizure action, not against the manufacturer but for the destruction of, say, 12 bottles of the product found on the shelves of a dealer, usually at some point far removed from the point of manufacture, such as in the State of Washington. The action is properly entitled like this, "*United States of America* v. *Twelve Bottles of Curex*" (or whatever the name of the product is). It is, literally, an action against those certain bottles of the product; the manufacturer is not a party to the action and if, as is usually the case, he does not become a party by entering an appearance, the action proceeds according to routine to a default decree of condemnation and those 12 bottles are smashed up under order of the court. Instead of compelling a proper change in the label the whole power of the United States Government has been called into play simply to smash up 12 bottles of valuable merchandise. When this procedure was written into the existing law 28 years ago it was probably put there with the idea of getting rid of worthless or dangerous products. If we had not become so accustomed to it during all of those years, we would not simply take it for granted without giving it any thought and would marvel at the stupidity of attempting to force compliance with the law by such clumsy, ineffective, ridiculous procedure.

The decree of the court ordering the 12 bottles destroyed does not effect any change in the labeling. The manufacturer simply sends the dealer another dozen bottles to replace those ruthlessly destroyed. It is cheaper for him and, if he does not want to make the change, better for him, simply to ignore the action and replace the merchandise for the dealer.

Nothing happens for several months. Then the judgment is published in the monthly "Notices of Judgments." Salesman of competitors of the manufacturer start carrying a copy of the notice of the judgment. When they call on a dealer who has "Curex" they express surprise and say something like the following. "Oh, do you sell Curex? Why, don't you know that the United States Government has condemned that product and has found that it is misbranded and will put anyone in jail who sells it?" This frightens the innocent dealer and he either ships his stock of the product back to the manufacturer or writes to him about it. It is a little embarrassing for the manufacturer and he must write explaining what has happened, that the question regarding the labeling of the product has not been tried out, that the dealer will not be sent to jail for selling it and that it is perfectly lawful for him to continue to handle it.

Similar letters from other dealers are received. The situation becomes more irritating to the manufacturer. Then he gets notice that the Government has seized a couple of dozen bottles of his product in the hands of a dealer down in Florida. He learns of seizures in New Jersey, Minnesota, California and Louisiana. About that time he either enters an appearance in one of the actions and commences a fight or he goes down to Washington to talk the matter over with the officials. Within a day or two, if he goes to Washington and is rightly disposed, he can usually convince them that he is right or they convince him that he is wrong and a label is agreed upon that is perfectly satisfactory to the Department and also to him.

Eventually the label change is made. But it has taken a year or two, has cost the Government a lot of money and has damaged the manufacturer's business. The delay, and also a large part of the Government's expense, can be better understood when one considers that the first action, under the existing law, is a court action involving an interpretation of the law and its application to label claims which will be binding upon the Department if the manufacturer enters his appearance and fights the case. Naturally the officials do not want a decision which may establish a precedent that will hamper their work. Accordingly, they do not commence the seizure action until they are ready for trial and are confident that they can go into court the next day and win the case. This necessitates the collection of samples of the product, chemical analysis of them and, usually, clinical experiments to establish the efficacy or lack of efficacy of the product. Scientists in different parts of the country conduct this work. Frequently it consumes a year and, considering the time of Department officials, must cost the Government thousands of dollars. All of this delay and expense is occasioned before the first move to correct the situation is made. And after action is started, often a year elapses before the manufacturer complies with the demands of the officials.

Notice that most of the delay and expense is occasioned by the fact that the first move on the part of the officials must be the institution of a court action.

Since before the pending bill was introduced I have advocated a constructive revision of the law, including an improved procedure. Let me outline my suggestions along this line. According to them, the improved procedure would work as follows:

If at any time the Secretary of Agriculture (that is, the Chief of the Food and Drug Control or his subordinates) believed a manufacturer was violating the law in any respect, the first action would be to serve him with notice to appear at a time and place certain, either in the District of Columbia or in the State where he had his principal place of business, not for a court action, not for a formal hearing, but for an informal conference. The purposes of the conference would be to come to an agreement: first, whether he was doing the act or acts; second, if so whether it or they violated the law; and, if so, to enter into a written agreement whereby the manufacturer would agree immediately to discontinue, to cease and desist from, the practice or practices.

If in pursuance to the notice the manufacturer appeared and signed such agreement, no harmful publicity would be given to the matter and nothing further would be done about it—so long as he complied fully with the written agreement. Because everything toward compelling compliance with the law would have been obtained.

But if the manufacturer failed to appear, or if he failed to enter into such written agreement with the Secretary, or, having executed such agreement, if he violated

it, then the Secretary (through the Food and Drug Administration) could at any time cite the manufacturer to appear at a time and place certain, in the District or in his home State, to show cause why the Secretary should not issue his cease and desist order commanding him immediately to discontinue the practice or practices. At the time and place set, a proper official of the Food and Drug Administration would conduct a formal hearing, would consider the evidence and testimony produced by the Department and by the manufacturer (respondent), would listen to arguments or consider written briefs and would make his findings either that the respondent was or was not violating the law, and, if he found that the law was being violated, would enter an order commanding the respondent to cease and desist from the practices.

Of course, to be constitutional, the law would have to provide for an appeal by the respondent to the courts. If he appealed the court would be empowered to take additional testimony in its discretion or to dispose of the case upon the record made at the hearing; it could either affirm the cease and desist order, set it aside, modify it in any respect, or do anything that the Secretary could have done before the appeal.

Once a cease and desist order became final, either because not appealed from within 30 days or because affirmed or entered by the court, the manufacturer would simply have to obey the cease and desist order or go to jail.

Note the simplicity, directness, and effectiveness of this procedure to compel expeditiously compliance with the law. The whole procedure would be remedial, not punitive, directed to compelling compliance and not to throwing a man in jail. Also note that the Department could start such remedial action immediately, without any extended or expensive preparation for a suit in court.

And note that this procedure would prevent the ruthless and useless destruction of valuable property just to effect a change of labeling, and would accomplish just what should be done without damaging unnecessarily the respondent's business or subjecting it, before any legal adjudication, to harmful publicity. Until a cease and desist order had become final and binding no publicity regarding the matter could be given out, because he had not been convicted of violating the law. But once the cease and desist order had become final and binding, such order would have to be published. But the Secretary would also be obliged to publish the final disposition of the matter upon appeal, whether favorable to the administration or to the respondent.

One other point in this connection. I think that if, upon appeal, the court should decide that the respondent had not violated the law, he should recover his costs including attorney's fees. This for two reasons. First, because he ought not to be compelled to stand such expense simply because of the mistake of the enforcing officials; their mistake was made for the benefit of all of the people in the interest of law enforcement and the expense should be borne by the Government. Second (and for this reason the law should provide that such costs must be paid to him from the appropriation of the Food and Drug Administration), to discourage the Administration from issuing cease and desist orders lightly and without sufficient reason. If the officials knew that in case they issued a cease and desist order improperly, the respondent could appeal and probably have it set aside by the court and recover his costs out of their appropriation, they would be careful to issue cease and desist orders only when reasonably satisfied that they would be sustained by the court. The contest between the average manufacturer and the Government is on a basis far from equal; the officials have the full power and resources of the Government behind them and stand to lose nothing. The manufacturer has only his own resources and frequently stands to lose all. Many a poor devil has been litigated to the wall by Government officials. This should not occur.

This plan for remedial procedure has been advocated by me consistently for a long time. Early last May, before this bill was introduced and before it was supposed to have taken shape, Mr. Eisenhower, Director of Publicity for the Department of Agriculture, with whom I had discussed my ideas for constructive revision of the present law, requested me to embody them in a letter to Professor Tugwell. This I did in a letter dated May 13, 1933, in which I told the Professor that I was writing him at the suggestion of Mr. Eisenhower. In that letter I wrote, on this point:

"I come now to a suggestion which, so far as I know is original and which I think, and believe you will think, is unselfish and constructive. I think the present set-up for enforcing regulation of label claims, standards of products and advertising representations is clumsy, unwieldly, inconvenient, inadequate, and too expensive as well as unduly harmful to legitimate business. The method of

suppressing unwarranted label claims and forcing the removal of substandard products from the market by seizure in livel actions is not sufficiently direct. The distribution of enforcement powers between the Food and Drug Administration and the Federal Trade Commission is senseless and unsatisfactory; all of the regulatory power in the food and drug field should be vested in the Food and Drug Administration. The injurious publicity that attends Governmental action before the manufacturer or advertiser has been given a fair trial and found guilty is unnecessary, un-American and unfair.

"My suggestion is that all regulatory power over food and drug products, labels and collateral advertising be vested in the Food and Drug Administration; that when the Administration has reason to believe that a product, its trade name, label claims, or collateral advertising is unwarranted it should first, except in cases where danger to human life is involved, be compelled to summon the manufacturer or advertiser to appear informally for a disdussion of the matter in an effort to secure voluntary change or withdrawal of product, name, label claims or advertising statements, before taking any other regulatory action; that only in event such informal action fails or the manufacturer or advertiser fails to appear, a forma citation should issue commanding him to appear at a time and place certain to show cause why a cease and desist order should not issue commanding him to discontinue the product, name, label or advertising statement, and an appropriate complaint should be served upon him detailing the alleged violation of law; in reasonable time a hearing should be had an the complaint either dismissed or a proper cease and desist order entered; of course there would have to be the opportunity of appeal to the courts which would be empowered to affirm or set aside a cease and desist order; at no stage of the proceedings until a cease and desist order is actually entered (except where danger to human life exists or here there is reason to believe the manufacturer or advertiser is acting fraudulently or in intentional violation of the law) should any publicity be given because the manufacturer or advertiser has not been found, after fair trial, to be guilty. The cease and desist order should be enforcible by penalties. I think this procedure would be about as direct, expeditious and effective, with the minimum hardship to reputable manufacturers and advertisers, as any that has been proposed."

This procedure is recommended as remedial procedure, to compel compliance with the law, where a manufacturer or advertiser may be violating it but is not acting fraudulently or with criminal intent. It is not designed to prevent criminal prosecution for criminal violations of the law. Nor is intended to prevent seizure of products that are imminently and seriously dangerous to human life or health. And the prohibition against unfavorable publicity before a cease and desist order had become final should be worded so as to allow the Department officials to publish any warnings, notices, or information reasonably necessary to prevent imminent and serious danger to human health.

From my experience, I am confident that the "informal conference" recommended would take care of fully 75 percent of the cases arising under the law and would quickly, conveniently and inexpensively result in prompt and proper changes. At such conferences either the officials would convince the manufacturer who is rightly disposed, of his errors or he would convince the officials, and the situation would be corrected to the satisfaction of both the officials and the manufacturer with good feeling on both sides. And the public would be more effectively protected.

There might be 5 or 10 percent of the cases in which the manufacturer or advertiser would deliberately and stubbornly resist the efforts of the Administration; those cases could be taken care of by criminal prosecution when warranted or, much quicker and more effectively than under the present law by driving straight ahead for a cease and desist order against him. In perhaps 15 percent of the cases there might be a bona fide difference of opinion which would require a formal hearing and possibly court decision, but that could be had more quickly under this procedure than under the existing law.

5. I come now to the fifth point or fifth respect in which I believe the present law to be seriously defective and in need of revision. I am amazed that this point was entirely ignored in drafting the pending bill, but even more so that it appears to have been overlooked entirely by everyone who has appeared before this Committee and by everyone who has written any of the many articles regarding the pending bill. It is this. The existing law does not distinguish between purely remedial actions (to compel compliance with the law by direct, legal action) and criminal prosecutions (to punish willful and criminal violators of the act) and recognize the importance of fraud or criminal intent in criminal prosecutions, and its immateriality in remedial actions. Nor does the pending bill.

The officials complain, and rightly so, of the difficulty of proving fraudulent intent in seizure actions designed to bring about, eventually, complaince with the law; so they jump to an extreme and illogical position that criminal intent ought never to be required under the law and that manufacturers and advertisers should be thrown into the penitentiary for even unintentional and almost unavoidable mistakes in even trivial matters under the provisions relating to labeling and advertising. The opponents of the measure jumpt to the other extreme position, just as illogical and untenable, and contend that because no man under our laws and institutions should be branded a felon simply because of an inadvertent or unintentional mistake involving no malice, fraud or criminal intent, the officials ought not be empowered to compel changes in labeling or advertising practices to conform to the law unless they can prove by a preponderance of the evidence that the manufacturer or advertiser was acting fraudulently. Both positions are so absurd that one marvels.

A clear distinction should be kept in mind and written into the law, between remedial procedure and criminal prosecution. A man should not be criminally prosecuted unless he has violated the law willfully, fraudulently, maliciously, or with criminal intent.

On the other hand, any sensible and practically minded man should recognize that if a manufacturer or advertiser is not complying with the law, the officials ought to be empowered to compel him to observe it, and that it should be regarded as absolutely immaterial whether the individual believes or thinks he is violating the law. The only question should be whether he is conforming to it.

The pending bill is viciously defective in failing to make the distinction and in providing that manufacturers, advertisers, advertising agents, publishers, and radio-broadcast licensees may be branded as felons and thrown into the penitentiary for unintential and inadvertent mistakes in petty matters. But the existing law is seriously defective in requiring the Government to prove fraudulent intent or intent to mislead or deceive in actions brought simply in an effort to compel compliance with its provisions, as in seizure actions. In this respect the existing law seriously needs revision in the interests of public protection and to enable the officials to administer it effectively.

The law should be revised or rewritten and in its final form should be primarily remedial and only secondarily punitive.

6. There is one little word, "may", in the existing law which should be changed to "shall". In section 10 of the Food and Drugs Act, June 30, 1906, as amended, it is provided that, in seizure actions if the merchandise is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of the act, it "shall be disposed of by destruction or sale", and the act then goes on to provide:

"That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof."

I can best point out the practical workings of this provision by referring to a personal experience.

Several years ago the Department seized approximately $10,000 worth of a product manufactured by my company, not because it contended that the product was not a meritorious one but simply because of some wording on the label which it considered scientifically incorrect and improper. It had not raised with us the question of the propriety of the labeling and had the large stock of merchandise seized without warning or opportunity to change the labeling to conform to its views. I went to Washington, conferred with officials of the Department and soon agreed upon changes in the wording which were perfectly satisfactory to the Department and to us. We then applied for the return of the merchandise under the provision quoted above, agreeing to relabel the product according to the wishes of the Department with the new label and to post the bond for the faithful performance of that undertaking.

Originally the officials had claimed, or had alleged in the libel, that the very name of the product constituted misbranding but, after our "informal conference", no longer contended that the name of the product was improper or constituted misbranding. Neither did they contend, although it was alleged as a matter of form in the libel, that the wording of the old label which the Department alleged amounted to misbranding, had been incorporated on the label in bad faith or with intent to deceive, mislead, or defraud. Nevertheless the court refused (under a Department policy which it recognized and enforced as if it were law) to allow the property to be delivered back to us unless we would admit

every allegation in the libel (among other things, unless we would admit that we had acted fraudulently and that the very name of the product, worth to us $100,000, constituted misbranding). Rather than make such untrue admissions reflecting upon our honor and integrity and that would destroy our property in the valuable and proper trade mark of the product, we naturally refused to comply with the unreasonable demand and, under the order of the United States District Court, approximately $10,000 worth of valuable merchandise was ruthlessly destroyed. That case is not unique; it is typical of how this same provision in the existing law is administered by courts under the influence of the Food and Drug Administration.

The pending bill contains substantially the same provision. In this respect the present law should be revised to provide that in such cases, where the product is not dangerous and where the fault is only in respect of labeling which will be corrected, "the court shall by order direct" the return of the property. In advocating this change from "may" to "shall" I do it on the strength of my assertion that the case just outlined is not unique, that it is typical. I challenge anyone to prove that it is not typical. (This matter should be borne in mind when considering Mr. Campbell's frequent assurances that the fearfully broad and arbitrary powers that would be conferred by many provisions of the pending bill would be exercised only with reasonable restraint and with sympathetic moderation and unprejudiced understanding.)

7. This is the last respect in which I think the existing law needs changing and, because it is so well known, I shall simply mention it briefly. Under existing law manufacturers are badly damaged by unfavorable publicity given them by the Department before there has been any legal adjudication of violation of the law. Witness the recent governmental propaganda in support of the pending bill.

The present law should be changed to prevent any such unfavorable and destructive publicity regarding a manufacturer, advertising, or product until after conviction or legal adjudication regarding the product, labeling, or advertising—except where criminal prosecution is brought or such publicity is reasonably necessary to warn or protect against imminent and serious danger to human life or health.

I think it is perfectly clear that in these seven respects the existing law is either deficient, inadequate, or unwise and should be changed; that is, the existing law should be changed:

1. To bring under its operation cosmetics and physical appliances for which curative claims or representations are made;

2. To bring regulation of radio advertising of food, drug, and cosmetic products, within its operation;

3. To vest jurisdiction over advertising of food, drug, and cosmetic products in the Secretary of Agriculture (Food and Drug Administration);

4. To change the enforcement procedure so that the libel or seizure actions would be limited to cases in which the products are imminently and seriously dangerous to human life or health, and to provide for a remedial procedure to enforce compliance with the law regarding labeling and advertising and adulteration, by means of "informal conferences" and agreements and orders to cease and desist;

5. To provide that in criminal prosecutions under the act the Government must prove knowledge, fraud or criminal intent in order to convict, but that in seizure actions only the fact of imminent and serious danger to human life or health need be shown and that in the remedial procedure to enforce compliance with the provisions of the act the only question would be whether the act was being violated and the belief or intent of the respondent would be immaterial;

6. To change the word, "may", in the provision for the return of seized merchandise to the owner in seizure actions, to "shall", upon posting of proper bond, but to limit the provision for the return of merchandise to such as would not be, when relabeled, repackaged, or reconditioned according to the terms of the bond, dangerous to health or life;

7. To prevent all damaging publication by the Department regarding believed violations of the law, until after a cease and desist order had become final, except regarding criminal prosecutions and except for such notices, statements, or warnings as might be reasonably necessary to prevent imminent and serious danger to life or health.

Except for the weaknesses and deficiencies pointed out above, the existing law has proved to be practical, satisfactory, and of immense benefit to the country. These changes should be made but are all that are necessary or desirable.

It does not follow (as too many people have assumed as a result of the Department propaganda designed to force passage of the pending bill) that simply because the existing law is insufficient, the pending bill with all its arbitrary, bureaucratic, and destructive features should be passed. These changes recommended above could be effected in either of two ways, either by amending the existing law in those seven respects or by passing the pending bill after amending it so as to remove the unnecessary and impolitic, bureaucratic features and to incorporate the constructive features which I have recommended.

It could be accomplished most simply by a few amendments to the existing law and this would nullify the objections of opponents to the pending bill that its enactment would scrap a big mass and long line of well considered court decisions interpreting the act of 1906. I do not give much weight to the plausible argument that a rewriting of the law would scrap 20,000 decisions. All but a relatively few of those decisions—as a cursory inspection of the notices of judgments will disclose—add nothing to the interpretation of that act and are simply default decrees for condemnation of merchandise. Regarding the few decisions that have been of importance, the change would be immaterial because they decide points that were doubtful only because of the wording of the act of 1906 and which would be definitely settled beyond question by a proper wording of the new law, such as regarding necessity to prove actual fraudulent intent, or the reasoning embodied in them would have the same weight and force under the revision.

But the act of 1906 was a compromise measure and amendments have been slapped on it from time to time; it is not well drawn, ordered, or arranged and does not cover the whole field as would be desirable. The pending bill, with all its shortcomings and vicious and destructive measures, is much more scientifically planned or framed and does not provide an ideal skeleton or framework for a comprehensive law. I am vitally concerned in only two general objectives, first, the improvement of the law in the seven respects pointed out above (whether accomplished by revising the act of 1906 or by amending and passing the pending bill), and second, if that is done by enacting the pending bill, then in the elimination from it of all of its unnecessary, impolitic, and destructive features. I think it would be better to properly amend and pass the pending bill. Let me point out its worst features, those which should certainly be eliminated if it should be decided to amend and pass it as amended.

In this brief I will simply discuss them in general, and for more definite and explicit criticism of them and of all of the pending bill, section by section, I refer to my analysis of Copeland bill (S. 1944) and observation of July 7, 1933, and as revised December 5, 1933, a copy of which I will file with the committee, and a copy of which I will be pleased to send to any Senator, Representative, or other interested person upon request. And I will not attempt here to suggest the exact wording of amendments to effect my recommendations, but I will file with the committee suggestions for all amendments to the pending bill to effect my recommendations. And, so that it can be more easily studied in the form in which it would be if amended as I recommend, I shall file with the committee a copy of the pending bill as it would appear after being so amended.

1. One of the worst features of the pending bill is that it would be absolutely destructive of a great and perfectly legitimate industry, namely the prepared medicine industry. It does not directly and explicitly outlaw that industry; it would effect that unfortunate object indirectly and subtly, as a practical matter, through the operation of a number of different provisions which all focus at one point, the destruction of that industry. Most of those provisions relate to the advertising of drug products and impose such unreasonable and unnecessary restrictions as would prevent almost all advertising of prepared medicines—and I am referring to honest, ethical, truthful advertising. Those provisions would make such advertising so hazardous and so ineffective and unprofitable that it would be discontinued. That industry, like others, depends for its existence upon advertising. The result is that the pending bill, by effectively destroying advertising of prepared medicines, would destroy the prepared-medicine industry. I shall point out seven provisions which, together, would have that practical effect.

(*a*) Provisions in section 6 (a) and section 9 (a) provide that labeling of a drug product constitutes misbranding and an advertisement of a drug product constitutes false advertising, if it is "in any particular" untrue "or by ambiguity or inference" (implication?) creates a misleading impression regarding such product. (And these provisions apply to labeling and advertising of food and cosmetic products also.) Bear in mind that any misbranding or false advertising within the definitions of this bill would be a criminal offense punishable by imprisonment in the penitentiary, even though inadvertent and unintentionally committed. These provisions deliberately omit all such words as "fraudulent"

and "intentional", so that honest belief, upon adequate investigation of the truth of a statement or possible implication would be no defense.

It is queer that the framers of the bill did not distinguish between implication and inference and used the term, "inference." The writer, speaker, label, labeling or advertisement implies or may imply something; the reader infers or may infer something that may or may not be implied. The manufacturer, packer or seller should properly be held responsible for anything which he has implied, according to reasonable construction or interpretation, in his labeling or advertisement. But he should not be held responsible for inferences which some reader may possibly draw from the labeling or advertisement if the labeling or advertisement does not reasonably imply that. No manufacturer or advertiser can possibly anticipate or foresee all possible "misleading impressions" which some readers might draw or infer. Such loose,general, indefinite language has no proper place in any statute which is, as this bill would be, a punitive or criminal statute.

No manufacturer of drug products could run any advertising copy more than a few months without reasonably expecting to be thrown into the penitentiary, no matter how careful and conscientious he might be. It might be held that some reader could possibly "by ambiguity or inference" draw some "false impression" regarding the product.

Labels are by nature and practice more explicit and limited than advertising and do not need to have the snap, life and persuasive power of advertisements, so the application of this provision to labeling—although serious enough—is not nearly so bad as its application to advertising. This statutory definition of "false advertisement", in connection with the inhumane penalties for unintentional false advertising, would be sufficient to destroy practically all advertising of prepared medicines.

Certainly if the desirable revision of the existing law is accomplished by passing the pending bill after it shall have been properly amended, section 6 (a) and section 9 (a) should be deleted and in place of them and of all provisions of the bill pertaining to advertising should be enacted one simple, clear, effective sentence substantially like this:

An advertisement of a food, drug, or cosmetic shall be deemed to be false if it is in any material respect substantially untrue or reasonably likely to deceive or mislead.

(*b*) Paragraph (b) of this same section 9 provides that an advertisement for a drug product shall be deemed to be false "if it includes the name of any disease for which the drug is not a specific cure but is a palliative, and fails to state with equal prominence and in immediate connection with such name that the drug is not a cure for such disease." There is serious reason to doubt whether there really is any such thing as a "specific cure" for any disease; opinions of scientists differ. Certainly it is conceded that there are not more than probably three or five "specifics." If I am not mistaken the Food and Drug Administration "recognizes" four, and only four, "specifics"; for malaria, for syphilis, for leprosy and for diphtheria (and the "specific" for diphtheria is not a drug in its strict sense). The diseases just mentioned are not such that ordinarily any prepared medicine would be offered, or could be truthfully offered, as a cure for them. The effect, then, of this provision would be that every time an advertisement for a drug product mentioned the name of any disease it would have to be followed "in immediate connection with such name" by such a statement as "This product is not a cure for that disease." Imagine if you can the effect of that monotonous expression recurring every time any disease was mentioned. Imagine if you can the selling force or persuasiveness of such advertisements. This provision is analogous to one which, as Mr. Clinton Robb has suggested to the committee, would require every doctor to post over his door a big sign reading, "I do not cure any disease."

In view of a reasonable and necessary provision in the law prohibiting any food, drug or cosmetic advertisement to be in any material respect substantially untrue or reasonably likely to decieve or mislead, such a provision is absolutely unnecessary for the protection of the public and could have only one possible, practical effect, namely, to make any advertising of prepared medicines so ineffective and unprofitable that no manufacturer of suhc products could afford to advertise them. No plausible argument has been advanced, or could be offered, for its necessity in the adequate or reasonable protection of the public.

Paragraph (a) (1) of section 8 contains the same unreasonable provision but applies to labels instead of to advertising of drug products. In view of a necessary and proper provision requiring labels to be absolutely truthful and not misleading or deceptive, that provision is just as unnecessary and unreasonable in respect of labels as is its analogue regarding advertising.

Certainly if the desirable revision or rewriting of the existing law is accomplished by passing the pending bill after it has been properly amended, paragraphs (a) (1) of section 8 and (b) (1) of section 9 should be completely deleted and nothing substituted in their respective places.

(*c*) Another provision in the pending bill, just as useless, unreasonable and absurd, is the second part of that same paragraph (b) of section 9. It provides that any advertisement of a drug product shall be deemed to be false if any representation directly "or by ambiguity or inference" concerning the effect of such drug is made "which is contrary to the general agreement of medical opinion."

In the first place, it is frequently impossible to prove with any reasonable degree of certainty just what "medical opinion" is on a given point. Medical opinion is constantly shifting. What was held to be true yesterday is believed to be false today and may tomorrow be known to be true, or doctors may tomorrow think that they know it to be true. No one knows better than the medical men themselves that a large part of "medical opinion" has been, and probably is today, false.

Many of the discoveries in medical science have been made by the research departments of manufacturers. When a new formula or product is discovered or devised that has a curative or remedial effect theretofore unobtainable, a truthful statement of its actual effect is necessarily "contrary to the general agreement of medical opinion." Disregarding the practical effect which this absurd and unreasonable provision would have in discouraging research for the discovery of new products for the alleviation of human suffering, I ask: Has it come to this, in legislation for the benefit of a small professional class and to the injury of the whole people and destruction of a legitimate industry, that the United States would throw a man in the penitentiary for telling the truth honestly and fairly?

This provision would prohibit in advertising of prepared medicines statements that are absolutely correct and truthful, simply because of the mistaken opinions of others. Nothing more than truthfulness and fairness and absence of deception can possibly be required, with any show of justice or fairness or reasonableness. The standard for truthfulness in advertising should be truth. No advertiser should be jailed for telling the truth fairly, simply because of the false opinion of others.

As might be expected, an analogous provision forbidding upon labels or in labeling truthful and fair statements which might, at the time, be contrary to even false "general agreement of medical opinion" is included in the bill, in section 8 (a) (2).

Mr. Walter G. Campbell, Chief of the Food and Drug Administration, in his remarks before this committee has attempted, as he has in printed answers to serious objections leveled at the present bill, to answer this grave objection. The objection is so sound that nothing but a superficial answer can be made. Conceding that "medical opinion", or "the general agreement of medical opinion", is constantly shifting and is frequently false, he had the courage to suggest only that the burden of proving what that opinion might happen to be on a given point at a given time would rest upon the Government. I submit that that reply or answer of Mr. Campbell's to this objection, like most of his attempted rebuttals of other serious objections to the pending bill, is not only weak and unconvincing but that it is entirely superficial, goes only to the trivial matter of difficulty of proof and entirely ignores the gist of the objection which is that, under the provision, honest men would be declared felons and thrown into the penitentiary for telling the truth and solely because of the false opinions of others.

If the present law should be rewritten by adopting the pending bill, after making reasonably necessary and proper deletions and amendments, certainly part (2) of paragraph (a) of section 8 and part (2) of paragraph (b) of section 9, should be completely expunged and nothing substituted in their respective places.

d. I now direct consideration to a provision in the pending bill, which although it applies only to misbranding of drug products and not to advertising, would have probably the most destructive effect on the advertising of package or prepared medicines. The destructive character of the pending bill is nowhere more apparent than in this provision to which I now refer; it would destroy the prepared medicine industry by its direct application to labels and, even if that were not so, it would destroy that industry which must advertise to live, by making it utterly unprofitable and, therefore, impossible to advertise. I refer to the provision in

(2) of paragraph (e) of section 8 which provides that any drug product shall be deemed to be misbranded (if the product is one other than such as are recognized in the United States Pharmacopeia or National Formulary or supplements thereto) unless the label bears "the name and quantity or proportion of each medicinal or physiologically active ingredient thereof." This hits all secret formulae, practically all prepared medicines on the market. According to this provision not only the name but the quantity or proportion of each active ingredient would have to be stated upon the label so that every druggist in the country and every irresponsible competitor and trade pirate could not only duplicate the product but could prove to any potential customer that the two products were identical except for trade name. Here is the requirement in the bill (so long desired by one professional class and by it advocated) for full, exact, and explicit disclosure of all secret formulae.

In this connection permit me to quote one paragraph from that letter which I wrote on May 13 to Professor Tugwell at the request of Mr. Eisenhower of the Department of Agriculture, before the pending bill was introduced, the letter from which I quoted previously:

"I understand that there has been agitation for legislation requiring the complete formula for every drug product to be printed on the label. There is no justification for such requirement and it would be harmful. Such legislation is strongly advocated by the American Medical Association and the American Dental Association but those associations are not at all averse to governmental action that would injure the business of even ethical manufacturers of package medicines. I concede that when a product contains dangerous ingredients in quantities that might be harmful, it would be reasonable to require a statement of them on the label. There is no sufficient reason to require all ingredients to be listed, and to require publication of every formula would be absolutely vicious. There is very valuable property in many secret formulae of undoubted value. I do not think such legislation could be made to apply to existing products, because that would amount to depriving the owners of the formulae of property without due process of law. And for it to be enacted to apply to future products when a reasonable protection of the public does not require that, would simply injure the business of reputable manufacturers who now spend much in pure research work to develop valuable products, would discourage them from this constructive work and would make them common prey of trade pirates who would imitate their preparations and adopt identical statements of formulae.

Legislation requiring statements of ingredients should go no further than is necessary to protect the public from physical injury. If a product is of no value or if its therapeutic claims are unwarranted it should be retired from the market by the administration acting appropriately; but in a vain effort to prevent worthless products from appearing, legislation should not be enacted that would require the publication of all formulae and thereby injure and destroy legitimate business and deprive the public of the advantages flowing from the research and initiative of package medicine manufacturers. There is a proper field for members of the American Medical Association and there is a proper and useful field for manufacturers of high-grade package medicines; neither should be permitted to force through legislation not required for the public welfare and designed to benefit that class of citizens to the injury of the other class and of the public."

This provision in the pending bill, for full and exact formula disclosure is (1) unreasonable and unnecessary, (2) useless, (3) unjust, and (4) very unwise, impolitic and destructive. I will show why.

1. The provision to require full and exact formula disclosure is unnecessary and, therefore and in view of its destructive character, unreasonable. Reasonable, adequate, full protection of the public does not require disclosure of secret formulae and no tenable argument has been advanced, or can be advanced, for it. If products contain dangerous ingredients in quantities that might be harmful it would not be unreasonable to require a statement of the presence, or even percentage or proportion, of such ingredients, but even in such cases there would be no need for complete disclosure of the formulae.

Mr. Campbell argued (I do not have a copy of what he said and must depend upon my memory, so on this point and others I can quote him only in substance and according to my recollection) that some individuals are allergic to certain drugs, that they have the right to know whether such ingredients are incorporated in a prepared medicine which they are solicited to purchase and to use, and that therefore this provision of the pending bill is justified in the interests of the protection of the public. Like Mr. Campbell's answers to all of the other serious objections to destructive provisions in the pending bill, this one is inadequate, only specious and superficial. But this answer of his, like the preceding

one referred to, ignores the real gist of the objection and is so superficial that it is not even plausible once its evasion is pointed out.

If a person has an allergy for a particular drug (and I concede that some few individuals do) it is to the advantage of such individuals to know of the incorporation of that particular drug in any prepared medicine offered to them. But here is the point which Mr. Campbell ignores: It is not important or of any value even, to such individuals to know the exact quantity or proportion of that ingredient. And this provision does not stop with requiring the name of each ingredient; it would require—and this is what gives it its vicious character—a statement of the "quantity or proportion" of each active ingredient. His answer, as usual, falls short of answering the real objection.

If the reason suggested by Mr. Campbell for this provision is the real reason for its inclusion in the bill, then the bill should require that every ingredient in the product, whether active or not, be named. Because if an individual is allergic to a particular substance and that substance is incorporated in a prepared medicine, it makes no difference to the individual whether that substance is active or not.

Allergies are more common in respect of food products; there would be more reason to require every restaurateur to print, in juxtaposition with every item on his menu, a statement of every ingredient and of its proportion in every dish.

Bear in mind that the objection is not to a requirement for statement of the "qualitative analysis", that is simply a statement of the presence of each "medicinal or physiologically active ingredient"; the objection is to the requirement for statement of the "quantitative analysis" of the product, a statement of the "quantity or proportion" of all active ingredients. No manufacturer would seriously object to a requirement for a qualitative statement. In fact many State laws now require that, and veterinary medicines, such as we manufacture, all carry such statements. The objection is leveled at the requirement for qualitative and quantitative statements, and Mr. Campbell's answer is of possible validity only in respect of qualitative statements, statements to which the objection is not directed. Hence his answer is entirely aside from the point, has no bearing upon, and does not even begin to answer, the objection.

The requirement for full and exact formula disclosure on the label of every drug product is useless and would give no appreciable protection to the public because a statement of formula means nothing to the ordinary user of package medicines. And just to make it possible for physicians and veterinarians to prescribe such commercial products by formulae, instead of by trade name, is no sufficient reason for such destructive provision. Mr. Campbell here suggested that if people are going to "medicate" themselves they have the right to know the nature of the product which they propose to take. The fact is that this answer, like the others, is only superficial and ignores the fact that the statement of formula on the label would not enable the ordinary layman or user to "medicate" himself intelligently. The ordinary user of prepared medicines is no more capable of intelligently reading and evaluating a statement of formula on a prepared medicine than is the average member of Congress, not as much, and I am confident most Senators and Representatives realize that they cannot do it.

3. The provision in the pending bill for full and exact formula disclosure on the label of all prepared medicines is unjust because it would uselessly and without reasonable necessity wreck the prepared medicine industry—just for the benefit of a relatively small professional class and at very great injury and loss to the rest of the people. This is the practical way in which this provision would work if the pending bill should be passed with this unreasonable and destructive provision.

A customer would come into a drug store and ask, "Have you got a 12 ounce bottle of 'Curex'?" "Yes", replies the proprietor as he goes to the shelves and returns with a 12-ounce bottle of "Curex" in one hand and with a 16-ounce bottle of a product of his own manufacture exactly identical to "Curex" except for the trade name. "'Curex' is a splendid product and I will be very glad to sell it to you. But, really, all of my customers prefer to use this 'Crulex' which I put up myself for my trade. The two products are exactly the same. The only difference is in the name and in the fact that when you buy 'Curex' you have to pay 75 cents for only 12-ounces while you get 16 ounces of 'Crulex' for only 50 cents. You see, the reason why 'Curex' costs about twice as much is because you have to pay for the advertising of the 'Curex Company' and for the name. I would not ask you to take my word for the fact that the two products are identical. You see, under the new Federal Food, Drugs, and Cosmetics Act the 'Curex Company' is obliged to state its full and exact formula on the label, and you can see it here for yourself. And the same law makes me state the full and exact formula of my product on the label, here. That law is so

severe that neither they nor I would make a false statement. You can read the two statements and see for yourself that the two products are absolutely identical. It is just a question whether you want to pay twice as much to get that name 'Curex' on the label. It is a wonderfully effective product and I will be very glad to sell it to you if you prefer, but really all of my customers take the 16 ounces of 'Crulex' for 50 cents." Not one customer out of a hundred would take the "Curex'. And, because of that fact, the "Curex Company" could not afford to spend one penny advertising its product; its advertising and sales would cease and the company would go out of business. And the same would be true of most other manufacturers of prepared medicines.

Mr. Campbell's answers to this objection are as futile, superficial, and evasive as his answers to all of the other serious objections. As I remember, his answer is substantially that the objection that this provision would wreck the prepared medicine industry is silly or nonsensical for three reasons. Let me state each of those three propositions, and show how untenable and insufficient they are, separately.

First he tells you in substance, competitors of a prepared medicine manufacturer do not need his statement of formula in order to duplicate the product. This ignores the gist of the objection and assumes that the objection is that the package medicine industry would be wrecked by this provision because it would enable competitors and trade pirates to duplicate a product. That is only a small and least important part of the objection. The gist of the objection is that when the products are, as they could be, easily duplicated, the seller can prove to a potential customer, and can convince him from the label statements that the products are identical. This Mr. Campbell ignores. Many well-established prepared medicines are now duplicated by trade pirates, but such pirates cannot successfully cut into the established business to any appreciable extent for the simple reason that potential customers cannot, and will not, accept their representations that the two products are identical. One product manufactured by our company has been quite extensively imitated by trade pirates, but we have never felt any competition from them.

Mr. Campbell's second proposition, as I remember it, is that most valuable secret formulas are not secrets of composition but are secret processes or techniques of manufacture and that, since this provision under consideration would not compel disclosure of such secret processes, the argument that this provision is destructive is nonsensical. The sufficient rebuttal to that is this: Although a few secret formulas do involve secret processes or tricks of manipulation in the compounding of the several products, this is true of probably not more than one out of a hundred prepared medicines manufactured under secret formulas; the objection does not go to any assumed disclosure of a secret process in that 1 percent of the cases and does go to the 99 percent of the cases in which the secret is a secret of composition, of percentage or proportion. His answer entirely evades and ignores this.

As I remember Mr. Campbell's third proposition it is that, anyway, the owners of secret formulas in the prepared medicine field can, if they wish, protect themselves by patent. It is commonly known by manufacturers of prepared medicines and by all lawyers familiar with the law of patents, that it is practically impossible to get a patent on any particular combination of drugs, as in the ordinary prepared or package medicine. There is no need to go into this point any further; the Patent Office or any patent attorney will bear me out on this point. Besides, how can Mr. Campbell, himself a lawyer, suggest that a manufacturer can patent a prepared medicine which has been on the market for 10, 20, or 40 years, or when several other manufacturers have been putting out other products practically the same in chemical composition and action?

His answer to the objection that the enactment of this unwise provision would wreck the prepared medicine industry, is probably as nearly a valid argument as a man even as able and acute as he is, could devise, but it patently fails to even begin to answer the objection.

4. The enactment of this provision of the pending bill to compel full and exact formula disclosure on the labels of all prepared medicines would be very unwise and impolitic and to the serious injury of all of the people (except physicians, dentists, and veterinarians) for two reasons.

First, it would deprive the public of many prepared medicines which are sufficiently meritorious to be commonly prescribed by doctors and upon which mothers have depended for many years. And this, just to compel people to go to a physician whenever they have need for such a preparation, and to get it—or a prescription for it—from him for a fee. Besides ruining manufacturers of prepared medicines and driving almost all of them from the market, it would

grievously hurt hundred of thousands of retail druggists throughout the United States, a large part of whose volume of business consists of sales of prepared drug products. Many doctors would compound the medicines they prescribed. Mothers of this country (who, without understanding the vicious and destructive provisions of the pending bill, have been driven by unprecedented propaganda at taxpayers' expense, into blindly demanding passage of this pending bill) would be horrified if it should pass, to find that they could no longer purchase for their families such prepared medicines as Castoria, Feen-a-mint, Vick's Vaporub, antiseptic solutions for gargles, sprays and the like. And picture the plight of people living in remote parts of the country far removed from a physician, who could no longer procure the simple and proved prepared medicines, and the plight of the poor who could not afford to go to a doctor every time a cough remedy, antiseptic preparation, or simple laxative were needed.

Second, the enactment of this impolitic and destructive provision would deprive the public of the undoubted benefit of private research on the part of commercial institutions in the effort to discover and devise new products and preparations for the alleviation of human suffering. It would discourage such companies from that kind of expensive work by removing all incentive for it and by compelling them to turn the fruits of their efforts over to trade pirates to be exploited by such parasites at prices which would be ruinous to the originators. Under existing law such private companies can keep secret the formulae which they develop and they can make back the money invested in such research work. But if this mischievous provision should be passed, that would be no longer true and the public would suffer for the benefit of a small professional class.

Just as if this provision for complete formula disclosure were not enough, an "omnibus" provision is tacked to it authorizing the Secretary (Food and Drug Administration) to require any further information on the label "as he may deem necessary to protect the public health." As in all other parts of the pending bill where any authority or discretion is vested in the Secretary it is an arbitrary discretion to act "as he may deem necessary" or advisable, without any limitation upon his discretion by any such word as "reasonable" or "reasonably." (See point IX below.)

Besides being unnecessary, unreasonable, useless, unjust, unwise and impolitic, and contrary to the real and substantial interests of all of the people it would hurt publications which derive revenue from legitimate drug advertising, very much.

It is apparent that the necessary result of such a law requiring full formula disclosure would be to reduce tremendously all drug advertising. Mr. Charles P. Parlin, of the Curtis Publishing Co., the biggest and among the most reputable of periodical publishers, speaking on behalf of the Periodical Publishers' Association, ably pictured to the committee the effect which this provision, and the others designed to hamper advertising, would have upon publishers. He stated that a very small percent of the publishers were managing to keep from losing money heavily, and that this and those other provisions would simply push a large part of them into bankruptcy.

I think I have said enough to show that this provision alone would be sufficient to destroy the prepared medicine industry, to crush many publishers and to seriously hurt all of the citizens of the country except physicians, and with no compensating advantages.

If the Congress should decide to properly amend the pending bill, certainly provision (2) in paragraph (e) of section 8 should be completely stricken out and nothing substituted.

(*e*) I have pointed out two provisions of the pending bill section 8 (a) (2) and section 9 (b) (2) which would effectively prevent manufacturers of prepared medicines from publishing the truth on labels and in advertising and under which they would be thrown into the penitentiary because of the false opinion of others. I now direct attention to another provision forbidding the publication of absolutely truthful statements without any false or misleading implications in the advertising of drug products. Section 9 (c) discloses its purpose to be "To discourage the public advertisement for sale in interstate commerce of drugs for diseases wherein self-medication may be especially dangerous, or patently contrary to the interests of public health." It then sets out the names of some 36 diseases or conditions. Among others it lists appendicitis, carbuncles, diphtheria, measles, mumps, pneumonia, scarlet fever, sinus infections, and whooping cough. Probably there is no specific cure for any of these conditions in the field of drugs. No member of the medical profession can cure such diseases any more than any prepared medicine could cure them. But frequently doctors prescribe drugs or prepared medicines in such cases, which give blessed relief

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to the sufferer and which, while not a specific or cure, are of valuable assistance as an aid in the proper treatment of the disease or condition. Members of the medical profession do not hesitate to accept fees for "treating" such conditions. Some of the diseases mentioned, such as measles or mumps, probably do not require anything more than palliative measures and proper nursing.

The viciousness of this provision does not lie in a prohibition against advertising any drug product as a cure for any such condition; it consists of a prohibition against "any advertisement of a drug representing it directly or by ambiguity or inference (implication?) to have any effect in the treatment of any of" the named diseases, regardless of the truthfulness and fairness of such representation.

Certainly no package of prepared medicine should be permitted to be advertised or labeled as a specific, or cure, for any incurable disease, nor should it be permitted to be represented as of any value as an aid in the treatment of any particular disease or condition unless it is of real value for the purpose. This is more than taken care of by other provisions in the pending bill and would be taken care of by a simple and proper provision covering advertising and forbidding it to be in any material respect substantially untrue or reasonably likely to deceive or mislead. But this paragraph provides that, even when a product is of very real value in the treatment or care of any of the named diseases, it cannot be advertised even as of "any effect in the treatment" of any of the diseases listed in that paragraph. It would forbid what is truthful.

The effect of this provision would clearly be to drum up business for members of the medical profession and to bring advertising for the Journal of the American Medical Association, to drive people away from the druggists and to the doctors for prescriptions. The very language of this paragraph reads that its purpose is "To discourage the public advertisement * * * of drugs * * *." The paragraph then goes on to provide that such advertisements shall not be deemed to be false if disseminated only to members of the medical and pharmacological professions or if they appear "in scientific periodicals," such as the Journal of the American Medical Association. The language, "especially dangerous" and "patently contrary to the interests of public health" carries an implication which Congress should hesitate to make, namely, that all or most "self-medication" is dangerous and contrary to the interests of public health. It may reflect the attitude of the Food and Drug Administration toward prepared medicines and their manufacturers. (This has seemed to be indicated by Mr. Campbell's references to prepared medicines as "nostrums", and to "the mystery extensively capitalized in the advertising of nostrums for imaginary diseases, which is developed adroitly and effectively through advertising and which constitutes the urge for the purchase of drugs for self-medication".) If the attitude of the Department towards advertising of drug products corresponds to Mr. Campbell's attitude, as I drew an impression of it, I confess I have misgivings agout regulation of advertising by the officials of that Department except subject to convenient appeal to the courts.

I don't believe the Congress will want to declare to the people that all "self-medication" (the use of simple prepared medicines) is dangerous or contrary to the interests of public health, but the implication is clearly contained in the quoted part of the paragraph under consideration. And lest that implication might be overlooked, the paragraph ends up with a provision that it "shall not be construed as indicating that self-medication for diseases other than those named herein or designated by regulations of the Secretary under the authority hereof is safe or efficacious."

There is no need for me to argue the point that this paragraph would have the effect of discourgaing advertising on the part of manufacturers of prepared medicines; the very language of the paragraph explicitly states that that is its purpose. It forbids perfectly fair and truthful statements of fact. It would aid materially in making the advertising of prepared medicines unprofitable. With the other provisions of the pending bill all working towards the same objective of making it too hazardous and utterly unprofitable for the industry to advertise even truthfully and fairly, it would effectively destroy the industry.

This paragraph (c) of section 9 is not reasonably necessary for the protection of the public, especially if Congress enacts a sensible provision forbidding any food, drug, or cosmetic advertisement that is in any material respect substantially untrue or reasonably likely to deceive or mislead. The whole paragraph should be stricken and nothing enacted to take its place.

f. As if the other provisions of the pending bill to which I have referred might not be enough to effectively wipe out all advertising of prepared medicines and thereby destroy the package medicine industry, the framers of the pending bill have added another paragraph which would be very effective for that purpose. I refer to paragraph (i) in section 8 of the bill. It provides that any drug product is misbranded if it is represented to be a germicide, bactericide, disinfectant, or antiseptic and for use on or within the human or animal body, unless its labeling bears a statement of each such use and conspicuously "and in juxtaposition therewith, the method and duration of application necessary to kill all micro-organisms" with which it comes in contact when so used (unless it is represented as a germicide, bactericide, disinfectant, or antiseptic for only specific kinds of micro-organisms and gives that information in respect of killing all of such specific organisms).

Only germicides, bactericides, and disinfectants are supposed to kill micro-organisms; antiseptics may only inhibit the growth or multiplication of such organisms. Therefore I don't know how antiseptics are to be labeled and sold. I don't know how even germicides, bactericides, or disinfectants could be advertised and sold under such unreasonable provision. If this should become law it would be impossible to guarantee, as required, the conditions and time under which even germicides, bactericides, and disinfectants would kill 100 percent of the micro-organisms with which they come in contact. Mr. Campbell, when questioned by Senator Copeland regarding this matter, conceded that there would be difficulty in determining what the effect of such a product might be in the human body. He said he would grant that there is a difference between the determination of the action of a germicide in the testing laboratory and in the human or animal body. As a matter of fact, this paragraph would lay down conditions which manufacturers simply could not possibly meet, as was implicitly conceded in Mr. Campbell's replies to Senator Copeland.

No manufacturer could possibly prove under what duration of application in interior parts of the body, even a very effective germicide would kill 100 percent of the micro-organisms with which it might come in contact. It would be simply impossible of proof. One hundred-percent efficiency should not be required of any medicine or drug product any more than any practicing physician should be required to have 100 percent success in the treatment of disease cases. Mr. Campbell argued that some manufacturers of germicides and antiseptics make extravagant claims or use language that may create unjustifiable impressions. That is no reason why the law should lay down an impossible rule.

Some better, more practical and reasonable provision should be written, such as that a drug product should not be represented, in labeling or advertising, to have germicidal, bactericidal, disinfectant, or antiseptic properties unless, when used according to directions, it does in fact exercise such properties to an appreciable and reasonable extent that is of real benefit as an aid in the treatment of conditions for which the product is therein recommended. That is, if any such provision is needed. But there is no sufficient reason for any provision referring specifically to germicides, bactericides, disinfectants, and antiseptics, if the Congress will simply enact a provision forbidding advertisements of food, drug, or cosmetic products, that are in any material respect substantially untrue or reasonably likely to deceive or mislead.

This provision refers to labels, not to advertising. But it, together with the others to which I have referred, would destroy all advertising of prepared medicines and would be very effective in destroying the prepared medicine industry.

This whole provision, paragraph (i) of section 8 should be deleted, if the Congress should decide to pass the pending bill after properly amending it, and nothing should be inserted to take its place.

(g) I have already suggested that advertising of prepared medicines would be, not only too unprofitable, but that it would be too hazardous for manufacturers of such products to advertise. I have pointed out a number of provisions which either would destroy the effectiveness of advertising or are of such nature that an advertiser could not always comply with them even by the exercise of greatest care and prudence. Hence to attempt to advertise prepared medicines would be too hazardous for these two reasons: First, the bill is deliberately so drawn that even unintentional, inadvertent, or accidental violations of any of those unreasonable and impossible provisions would be a criminal offense; second, the penalties for such violations are so inhumane and severe that no manufacturer would run the risk involved in advertising.

That a manufacturer or advertiser of any food, drug, or cosmetic product could be convicted criminally and imprisoned every time he violated any of the provisions of the bill regarding adulteration, misbranding, or advertising—even if he did it inadvertently, unintentionally, with no reason to believe that he was violating the bill and in spite of all care and precautions to observe its letter and spirit—is apparent from a reading of section 17 which defines the criminal acts

and fixes penalties therefor. Paragraph (b) fixing penalties of fine from $100 to $1,000 or imprisonment for not more than 1 year or both such fine and imprisonment for a first violation, and sentences of imprisonment for not more than 2 years or fine from $500 to $3,000 or both such fine and imprisonment for any subsequent violation, clearly refers to unintentional violations without fraudulent or criminal intent. This is apparent from the deliberate omission of any word which, by judicial construction or interpretation could be held to import any knowledge, intention, fraud, or criminal intent. This is made certain by the following paragraph (c) which fixes the penalty for any "willful offense" at imprisonment for not less than 6 months and up to 3 years or fine of not less than than $1,000 and up to $10,000, or both such imprisonment and fine.

There is no need to dwell on the harshness, inhumanity and injustice of penalties up to $10,000 fines and imprisonment in the penitentiary up to 3 years for accidental violations that could not reasonably be avoided. They are shocking to an ordinary, unbiased and undistorted sense of justice and fairness.

I have sufficiently shown how all of those provisions which I have discussed individually, focus at one point, the practical elimination of drug advertising. The destruction or prevention of drug advertising would effectively destroy the prepared medicine industry. In the respects indicated the pending bill should be changed, if it is going to be passed, so as to entirely eliminate all of those unreasonable and destructive provisions. A sufficient provision to adequately protect the public and regulate all food, drug and cosmetic advertising, would be one substantially as suggested above.

II. The first of the worst features of the pending bill, which I have pointed out, is that it would be absolutely destructive of a great and perfectly legitimate industry. I did not point out all of the respects in which it would be destructive of the prepared medicine industry but pointed out only those provisions which would effectively cause that destruction by doing away with all drug advertising. There are other provisions in the pending bill which would effect also the whole drug industry and the food and cosmetic industries, and some of them will be mentioned. I do not contend that the bill would be so destructive in respect of other sections of the general drug industry. It would not wipe out the pharmaceutical industry; medicines would continue to be prescribed by physicians, druggists would put up prescriptions and, in so doing, would make use of drugs and pharmaceuticals. Manufacturers of pharmaceuticals and of crude drugs do not advertise their products to the public for use in treating disease conditions, so the provisions of the bill relating to drug advertising would not injure those branches of the drug industry as they would injure the prepared medicine manufacturers. It would not be absolutely destructive of the rest of the drug industry, of the food industry, or of the cosmetic industry. But those other industries would be seriously injured, not only by the provision branding as false any food, drug, or cosmetic if in any particular it is untrue or by ambiguity or inference creates a misleading impression, but by other provisions of the bill which will be pointed out and which apply to foods and cosmetics as well as to all drug products.

III. A third of the "worst features" of the pending bill needs not to be enlarged upon much, after what has been said. It is this: By practically wiping out all prepared medicine advertising and by seriously interfering with and discouraging food and cosmetic advertising, the pending bill would, if it should be enacted in its form as drafted, very seriously injure the whole publishing industry. Food, drug, and cosmetic advertising probably constitutes a good 50 percent of the total advertising in most periodicals; if this bill should pass a very large part of that would be lost to the publications. As Mr. Charles P. Parlin told the committee, during the past few years most publishers have been "going into the red". If they lose any considerable part of their present advertising lineage, many will be forced into bankruptcy which, of course, will throw many thousands of men and women out of useful employment.

IV. The next of the "worst features" of the pending bill as drawn, I will simply point out. From what I have already said this is sufficient. By destroying the prepared medicine industry it would deprive the people of all of the useful and proved package medicines upon which they so largely depend, all medicines sold under trade names and manufactured under secret formulae. Besides injuring all of the people except a small professional class, this would hurt most seriously people living in remote parts far removed from physicians and who must keep in their medicine chest an adequate supply of such simple remedies for meeting ordinary emergencies and the simple ailments in life. Also a large class of the people cannot afford to call a doctor except in case of serious illness.

V. It is enough to simply point out that this same destruction of the prepared medicine industry would have a most serious effect on most druggists. A large part of their volume of sales consists of sales of prepared medicine. Practically none of them could stand to lose this immense part of their business without being very seriously injured, and many would be pushed to the wall. But as I have shown, that part of their business would necessarily be practically wiped out if this bill should pass with these unreasonable and destructive provisions. Therefore this is one of its "worst features."

VI. One of the worst and most vicious features of the pending bill has been pointed out before the committee but has not been adequately presented. I refer to its provisions for licensing and inspection. These provisions are contained in sections 12, 13, 15, and 22. Although this bill does not specifically make it mandatory for all manufacturers of food, drug, or cosmetic products to obtain a license from the Secretary if they are to continue in business, it confers upon him such broad power that he can, as a practical matter, require any such manufacturer to go out of business unless the manufacturer accepts a license from him upon almost any conditions he may see fit to fix regarding the operation of the plant. The Secretary need simply "find" that the distribution of any of the products may (not that they necessarily will or reasonably may), by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health and that such injurious nature cannot be "adequately" determined after such articles have entered interstate commerce; then he may "after notice and hearing" "make such regulations governing the conditions of manufacture, processing, or packing as he deems necessary to protect the public health" and require the manufacturers, processors, and packers "to hold a permit conditioned on compliance with such regulations." Since almost any food, drug, or cosmetic product could possibly be injurious through mistakes in preparation or compounding, and since the Secretary could decide that such mistakes could not be "adequately" determined after the product had left the plant, this provision practically gives him an unlimited discretion to license any food, drug, or cosmetic manufacturers (sec. 12 (a)).

The next paragraph (b) of section 12 authorizes him to issue such permits for any such periods of time as he may by regulation prescribe and to make any regulations regarding their issuance and renewal. He is authorized "to suspend immediately upon notice" any permit—that is without any warning, hearing, or opportunity for defense and without going into court; he could do this whenever he "finds" that "any of the conditions of the permit have been violated", regardless of how slight the danger to health might be as a result of the violation of some condition of the permit. No manufacturer could afford to try to question or resist even an unreasonable regulation or condition. If, after his permit has been thus revoked, the manufacturer shipped one package he could be jailed for 1 year and fined $1,000 or both; if he shipped a second package he could be fined $3,000 and put in the penitentiary for 2 years and if the court found that he did this wilfully or with knowledge that his permit had been revoked the court must imprison him for at least 6 months and up to 3 years or fine him not less than $1,000 and up to $10,000 or inflict both the fine and imprisonment (see sec. 17 (b) and (c)) for each shipment.

Under these provisions of section 12 of this bill the Secretary could by regulations and licenses or permits, control just about everything concerning personnel, formulae, methods of manufacture, equipment, plant and of working conditions, because they could all possibly affect health and because no manufacturer could afford to dispute his authority or try to resist.

The last paragraph (c) of section 12 provides that "any officer or employee designated by the Secretary shall have access to" any establishment operating under permit, "for the purpose of ascertaining whether or not the conditions of the permit are being complied with." Such access or permission to examine anything the inspector cares to investigate, had better not be denied because such denial is "ground for suspension of the permit."

It is not only such manufacturers, processors or packers of food, drug or cosmetic products, as have been put under permits or licenses by the Secretary, that are subject to "inspection" by inspectors on the payroll of the Food and Drug Administration or of the Department of Agriculture. The first paragraph (a) of section 13 provides that any officer or employee commissioned by the Secretary, if he first obtains the permission of the management, may enter any plant in which "food, drugs or cosmetics are manufactured, processed, packed or held for shipment" and may inspect it "and all equipment, methods, processes, finished and unfinished materials, containers and labels." The expression "after first obtaining permission" of the management is a "joker" and conceals on casual

reading the full import of this provision. Because, to insure that the management will not withhold such permission, the second paragraph (b) provides that whenever such permission is withheld for an inspector to do any of those things the United States district courts can issue an injunction, either temporary (before any hearing) or permanent, to restrain the movement of any products from the plant into interstate commerce, until the permission is given, and to punish summarily for contempt any violation of such injunction.

It is all very well for Mr. Campbell to tell the committee that neither he, the Secretary, nor any of the officials of the Food and Drug Administration intend to missuse, or use harshly, any of the broad and unlimited powers which would be conferred upon them if this bill, in its present form, were enacted. But this bill is not proposed as temporary or emergency legislation; it is presented to become the permanent law. The time will come when neither Secretary Wallace nor Mr. Campbell will be in office and when the law will be administered by others who may not be so fair minded or practical. And it should be remembered that most of the powers would be exercised necessarily by a horde of inspectors. No powers so unlimited, arbitrary, bureaucratic and despotic should be permanently vested in any public officials, powers of life and death over three giant industries.

Note that the Food and Drug Administration would have to provide out of its appropriations for the salaries of inspectors and expense of inspections under section 12 and section 13. Such inspections, conditions for licensing and cancelation of licenses or permits could be carried out in a most galling and oppressive fashion. Unless I entirely misunderstand human nature and the desire to extend the operation of bureaucratic activities further than Congressional appropriations will usually permit, the powers under these two sections are very likely to be exercised in such a way that the average manufacturer will elect to "voluntarily" apply for the "voluntary inspection service" cleverly provided for in section 22. This will relieve the Administration of all expense in the matter of managing or "regulating" business, so that it can, without increasing its expenses or need for heavy appropriations, enlarge its force of supervisory inspectors just as far as politics and bureaucratic policy or ambitions may dictate. (See sec. 22.)

Section 22 provides for the voluntary inspection service. Under its provisions the Secretary may, upon "voluntary" application of any manufacturer or packer of foods, drugs or cosmetics, appoint "supervisory inspectors" to examine and inspect all premises, equipment, methods, materials, containers and labels used by the manufacturer or packer. Here, then, is the bait to induce manufacturers to be hooked; if, and so long as, everything is found to conform to the provisions of this bill and to all "regulations", a manufacturer may be authorized to attach some kind of seal of approval of the Department on his product.

Under the practical operations of the law it probably will become advisable for every manufacturer of food, drug or cosmetic products "voluntarily" to apply for this "service."

Of course, it will require thousands of supervisory inspectors to inspect and regulate all of the plants; the Department could not hope to get sufficient appropriations to enable it to support such a host of tax eaters. So point number one (of the two-pointed hook) is that the manufacturer shall pay fees to be fixed by regulations in such amount as to cover the cost of the supervisory inspection and examination, together with the reasonable costs of administration. The other point of the hook is that the concern will practically pass under the management of the Food and Drug Administration regarding all matters of plant, personnel, equipment, formulae, methods, and operation.

I don't think there is any doubt but that, if the bill becomes law, the Department will push the expense of inspection off on the manufacturers by making it very advisable that they voluntarily apply for this service. They will get inspection anyhow, under the licensing provision (sec. 12) or under the factory inspection provision (sec. 13), and the supervisory inspectors under the voluntary inspection service will probably be much more reasonable fellows and much easier to satisfy than the inspectors sent out to noncooperating manufacturers, under those other two sections and at the expense of the Food and Drug Administration.

Under these sections the Administration can put over a gigantic plan for the management and control of those concerns and at the manufacturers' expense.

If this bill becomes law the chief of the food, drug, and cosmetic control will become a powerful man with an army of underlings and will be czar of the food, drug, and cosmetic industries. He will be treated with deference and regarded with fear and trembling by them and by all publications that carry food, drug, or cosmetic advertising and by the radio industry. Managing, supervising, or regulating concerns that now do a business running into the billions of dollars

annually, he should then be entitled to a big salary. He will be able to pass out lots of patronage for the political party in power. Probably the concerns that exist only at his will, or which he could effectively put out of business, will be willing to make voluntary and substantial contributions to the campaign fund of the political party represented by him or by his Secretary of Agriculture; it will take only the tactful suggestion of the supervisory inspector in charge of the particular plant that it has been put down for $1,000 or $10,000 as the case may be.

I think that this section 22 is one of the cleverest in the whole bill. Officials of the Food and Drug Administration realize that it would be impossible to get sufficient appropriations from Congress to support the whole army of inspectors that they would like to have under them and that would be necessary in order to control and manage all the food, drug, and cosmetic plants of the country as they want to manage and control them. So this plan to get the effective management of the plants and at the same time make the manufacturers pay the entire load was devised.

It is common knowledge among those familiar with the workings of the Food and Drug Administration that officials of that Administration have desired, for years, to obtain such power to regulate or control the food and drug plants of the country by supervisory or managing inspectors. But heretofore the impossibility of procuring the necessary congressional appropriations has stood in the way. There is no reason to believe that this power, if granted by enacting those provisions of the pending bill, would not be exercised. It has been estimated that there are in the country 40,000 plants in which the Department could put its inspectors under these provisions. It would be a most dangerous and impolitic thing to authorize the creation of this immense political army living like parasites on the three industries which they would control and regulate, and for all practical purposes manage, if not destroy.

These provisions would create stupendous, almost unlimited opportunities for graft. Such supervisory inspectors could decide to junk equipment and compel manufacturers to install other machines according to specifications fixed by them and which would necessitate the purchase of equipment from particular manufacturers. Also a supervisory inspector in a particular plant, having access to all formulas and processes, would be bound to learn important trade secrets. When he went to a competing plant there would be serious danger of his unintentionally divulging such secrets and venal men could be induced to do so for a proper consideration. No matter how high-minded the Secretary and Chief of the Food, Drug, and Cosmetic Control might be, they could not always make wise appointments and among the 40,000 supervisory inspectors it is reasonable to presume there would be many unfitted by natural ability, training, and experience to exercise such vast responsibilities. It would be like the army of prohibition agents or inspectors who have so frequently disgraced their country.

If Congress should decide to properly amend and revise the pending bill and then pass it, sections 12, 13, 15, and 22 should be entirely expunged and nothing enacted regarding inspection or licensing.

VII. Another of the worst features of the pending bill as drafted is a feature of the present law, but in the pending bill it is greatly increased or aggravated. I refer to the provisions authorizing the Department to publish, without any limitation or restrictions, any information deemed advisable and which might seriously hurt manufacturers who have been given no opportunity to defend themselves.

Section 21 authorizes the existing legal blackmail by which the Department distributes at public expense and all over the country reports (before any trial, opportunity for defense, or judicial finding) which are frequently very damaging to the manufacturers whose names and products are mentioned or referred to. Worse, under the provisions of this section the Secretary can publish any such information regarding any food, drug, or cosmetic as he deems necessary in the interests of public health and for the protection of the consumer against fraud. This can be done without any conviction, hearing, or opportunity for defense and only the Secretary is the judge regarding what information shall be distributed and the frequency and extent of such distributions at public expense. There would be nothing to prevent him from deeming information to be in the interests of public health or for the protection of consumers against fraud although it would be of little or no interest except to discourage self-medication or to otherwise educate the public up to calling in their physicians and veterinarians more frequently, to point out the dangers in the use of package medicines, to educate the people to demand the Department's seal of approval on products or to otherwise injure the package medicine industry.

The Government propaganda or publicity which has been broadcast to work upon the emotionalism of the women of this country and to move them to blindly demand passage of the pending bill without any intelligent understanding of its bureaucratic and destructive provisions, by press releases, talks by representatives of the Department before women's clubs all over the country, by radio, and on motion picture screens throughout the country, including the widespread exhibitions of Professor Tugwell's so-called "chamber of horrors"—all designed to create prejudice against food, drug, and cosmetic manufacturers—suggests what kind of publicity could be expected under the provisions of section 21 of the pending bill, even when the administration of the law would be in such capable hands as those of Secretary Wallace, Professor Tugwell, and Mr. Campbell. There is no way to anticipate what the publicity might be if men less fair-minded, high-minded, broad-minded, and conservative might some day be placed in the administration of the law.

If Congress should decide to properly amend the present bill and pass it, section 21 should be entirely deleted and nothing enacted in its stead except a proper provision, which I shall suggest, to prevent all harmful publicity with identifying reference to the manufacturer, advertiser, or individual concerned until he should have had an opportunity to defend himself and there had been a legal adjudication of guilt, except in criminal cases or where notices or warnings might be reasonably necessary to prevent imminent and serious injury to health or death.

VIII. Another of the "worst features" is section 23 vesting in the Secretary (Food and Drug Administration) unlimited power to enact any regulations "he may deem necessary for the efficient enforcement of the functions vested in him by the provisions of" this bill, "including regulations with the force and effect of law" vesting in him and his subordinates all of the stupendous powers created by sections 9 and 10 of the Federal Trade Commission Act.

Paragraph (a) of section 15 should be read in connection with section 23. Together they provide that the Secretary through any employees of his Department or through any food, drug, or health officer of any State, Territory, or county duly commissioned by him, may conduct examinations and investigations, like the Federal Trade Commission, anywhere in the United States and may compel the attendance of any witnesses and production of any documents just like that Commission and that, as in the case of the Federal Trade Commission, "The findings of fact by the Secretary shall be conclusive if in accordance with law", so as to make it impossible for the courts to reverse the decision of the Secretary or his underlings if there is any evidence by which their findings could be sustained. For the full effect of section 23, sections 9 and 10 of the Federal Trade Commission Act must be consulted. Among other things it provides that if anyone neglects or refuses to attend and to testify or to produce any documentary evidence in his power in obedience to the subpena he shall be punished by a fine of from $1,000 to $5,000 or imprisoned for not more than 1 year or both.

If the Congress should decide to properly amend the pending bill and pass it, all of section 15 and all of section 23 should be stricken. The Secretary should be given "reasonable" discretion and powers to establish regulations within limited fields and if any provision is enacted to give any special effect to his findings, it should provide that they should be, not conclusive, but prima facie if in accordance with law. I shall suggest amendments on these points.

IX. The last thing about the pending bill that I shall refer to, is one of the worst. It gives the bill its bureaucratic character. But I shall not enlarge upon that characteristic because it has been emphasized by other and is patent upon a most cursory reading of the bill. It is the frequent grant of unlimited power, in nearly every section, with no words of limitation or restriction. I don't think the word "reasonable" or "reasonably" can be found in the entire bill. The Secretary would be authorized to make just about any regulation or do anything as he might deem advisable.

It is suggested by the Department that even in the absence of any words of limitation, the courts would construe any grant of authority to be a grant which could be exercised only within reasonable bounds. There is something to this suggestion but it is misleading and the more so because there is some element of fact to it. Without any words of limitation in a particular grant of authority the courts could enjoin or set aside official action clearly so arbitrary, despotic, and capricious as to amount to a taking of property without due process of law. But where, as everywhere in the pending bill, discretion or authority is deliberately conferred without any restriction or words of limitation, the absence of any limitation is not without significance.

The courts must recognize the legislative intent to vest the fullest discretion and broadest possible power in the official and to make him the sole judge regarding its exercise wherever reasonable minds could possibly differ. It would be much more difficult for the courts to reverse or nullify his particular action in a given case, than if the grant of power were to "reasonably find" or make "reasonable regulations" or regulations "reasonably necessary for the protection of the public." With such words of limitation, the courts could not set aside any reasonable action but would always be able to pass upon the reasonableness of the action.

If, as is suggested, the words "reasonable" or "reasonably" would be read into the act by the courts, what is the objection, when the law is being written, to writing those words into it in order to avoid any question, instead of taking chances on the courts reading into the act something which the Congress refused to write into it?

My observations are similar regarding the last sentence in section 23 of the pending bill: "The findings of fact by the Secretary shall be conclusive if in accordance with law." This does not mean that the courts could not set aside any finding of fact regardless of how frivolous or contrary to evidence it might be. But it is not without significance and was inserted in the bill intelligently and advisedly. Its effect would be to make it much more difficult and unlikely for a court to reverse a finding of fact by the Secretary. It would prevent a court from setting aside a finding even where the evidence was such that the court would certainly have found otherwise, but where it could not say that reasonable minds could not possibly differ.

Like the deliberate omission of all words of limitation or restriction in all provisions granting discretionary powers, this provision that the Secretary's findings shall be conclusive would have the effect of making his findings, as his discretionaries, acts would be, just as free from reversal by the courts of the land as it is possible, under our Constitution, to make them. It is impossible absolutely to oust the courts of jurisdiction to interpret the Constitution and laws, but this bill is designed to restrict their action as far as is possible.

The pending bill, besides having the bad features which I have discussed and others which are specifically pointed out, section by section, in my analysis above referred to, is deficient in several of the respects pointed out in the first part of this brief regarding the existing law, especially in failing to provide a simple, direct, expeditious, and remedial procedure for compelling compliance with the law and in failing to include criminal intent in definitions of crimes; also in failing to limit seizure actions to cases where products are imminently and seriously dangerous to human life and in failing to forbid unnecessary and harmful publications before legal determination of violation of the law.

Regardless of its bad features and deficiencies, the pending bill offers a comprehensive, orderly plan for a reasonable, workable law. By proper deletions, amendments, and additions it can be made into a splendid statute that will do in a practical way all that should be done, one which will insure adequate protection to the public without injustice to any citizens, without unduly hampering legitimate business or setting back economic recovery. To so improve it will require considerable amending, but the results would well justify the work involved. As a supplement to this brief and as a part of it I am filing with the committee my suggestions for the specific amendments to the pending bill, S. 1944, which would accomplish all of my recommendations, and I urge that the pending bill be reported out with recommendation for amendment in those respects and passage.

Respectfully submitted.

DONALD J. BURKE.

ANALYSIS OF COPELAND BILL, S. 1944, AND OBSERVATIONS

Section 2: This section defines the principal terms as used in the bill.

"Food" is defined to include "all substances and preparations used for, or entering into the composition of, food, drink, confectionery, or condiments for man or other animals." The definition is unscientific because it makes use of the term "food" in defining that very term. Note that it includes in the category food all substances or products that are confectioneries and that it does not exclude medicated "foods", such as laxative breakfast foods, medicated fruits, candies, and gums. Such medicated foods or confectioneries are really medicines put up, to be more palatable, in the form of food, gum or candy, and in fairness to the manufacturers thereof and for the protection of the public should be classed as drugs and subject to all of the provisions governing the manufacture, labeling,

advertising, and sale of drug products, and they ought not to be regulated under the provisions applying to foods.

The result of putting confectioneries (medicated as well as unmedicated) in the category food and in not excepting medicated foods from the classification is to give to the Food and Drug Administration the power to wipe out the business of manufacturers of laxative candies, medicated gums, laxative breakfast foods, medicated fruits, and the like. This is accomplished in the bill by including a proper provision that the Secretary of Agriculture may, by regulation upon notice, forbid the incorporation of any poisonous substances in foods (sec. 10) and by providing that, to do so, all he has to do is "to find" that the poisonous substance or drug "is or may be injurious to health" (which means "may possibly be") "taking into account other ways (evidently ways other than according to the directions on the product) in which the consumer or user may (i.e., 'may possibly', not 'may reasonably') partake of or be exposed to" it. Without the inclusion of the unqualified "mays" and the latter provision (which enables the Secretary to base his findings upon what might happen if a person tried to commit suicide with the product or if he totally disregarded the directions) the section would not be unreasonable. There is more danger to human life in bichloride of mercury tablets and in many other drugs frequently kept in the medicine chest than there is in these medicated breakfast foods, gums, and candies. The definition of food—without reference to section 10—seems harmless enough, just as the threatening character of the power conferred by section 10 is not apparent unless read with reference to that definition.

The logical way to exclude this effect is to rewrite the definitions of "food" and "drug" so that the kinds of products I have referred to will be classified—as they should be classified—under "drugs".

The other definitions in this section do not require special comment except to point out that the term "drug" is defined broadly enough to include mechanical appliances used to correct body infirmities and that the term "cosmetic" is defined so that cosmetics can be brought under the operation of the new law. I think there is sufficient reason to bring such mechanical appliances and cosmetics under Federal regulation.

One other point. The definitions distinguish between "label", "labeling", and "advertisement". The term "label" is limited to the principal labels upon the immediate container and upon the outside of any container or wrapper of the retail package. The term "labeling" includes labels and extends to all written, printed or picture material enclosed in, or accompanying, the product, and thus clears up a point concerning which there has been some question, namely whether the Food and Drug Administration had jurisdiction over printed matter enclosed in the package but not specifically referred to on the label. The definition of the term "advertisement" is broad enough to include all written, printed or verbal representation of fact "or opinion" regarding the product whether in booklet, leaflet, poster, periodical advertising, letters, or statements made by salesmen, and includes a means of advertising that needs regulation badly, namely radio advertising. In my opinion, the definitions of "label" and "labeling" are satisfactory and I think that it is very desirable that the provisions applying to advertising be extended to radio advertising.

I have said that the definitions for "food" and "drug" should be rewritten. The following could be improved, no doubt, but as a suggestion I submit the following definitions for those two terms and for "cosmetic":

Section 2: As used in this act, unless the context indicates otherwise:

(a) The term "food" includes all substances and preparations other than drugs, designed, advertised, or represented in labeling thereof, to be eaten or drunk by man or other animal.

(b) The term "drug" includes (1) all substances and preparations then recognized in the United States Pharmacopoeia or National Formulary or supplements thereto; and (2) all substances, preparations, and devices represented in labeling or advertising thereof for use in or on the human or animal body in the cure, mitigation, treatment, or prevention of disease or to affect the structure or function of such body or of any part of it.

(c) The term "cosmetic" includes all substances, preparations, and devices other than drugs and foods represented in labeling or advertising thereof for use in cleansing or caring for the surface, or any part of the surface, of the human body including eyes, ears, nose, mouth, teeth, lips, throat, nails, scalp, and hair.

Some such definitions as these would bring under the operation of the provisions applying to drugs anything to be eaten or drunk and all substances, preparations, and mechanical devices, for which any medicinal, curative, remedial, or therapeutic claim or representation for use in or on the human or animal

body is made; anything to be eaten or drunk and for which no such claims are made, would fall under the classification "food" where it belongs; and any substances, preparations, or devices for which no such claims are made and which are not to be either eaten or drunk but which are for use in cleansing or caring for the surface of the body would come under the category "cosmetic". With this kind of definitions in section 2, section 10 would probably be quite proper.

Section 3. It should be noted that the bill provides that a food shall be deemed adulterated if it is "or may be" dangerous to health or if it has been prepared, packed, or held under unsanitary conditions whereby it "may" (a) (4) have become contaminated; also if any substance has been mixed or packed therewith so as to increase its bulk or weight, "or" reduce its quality or strength "or" create a deceptive appearance. Inasmuch as almost any product which comes within the definition of the term "food", could possibly be "dangerous to health" if it has been prepared, packed, or held under conditions less than ideal, it is unfortunate that the bill does not include the word "reasonably" to make the sentence read that the food shall be deemed to be adulterated if it is or may reasonably be dangerous to health. Most, if not all, food products could become contaminated when prepared, packed, or held under unsanitary conditions, and the term "unsanitary" is relative and indefinite; hence this provision is very far-reaching and capable of great extension by judicial and executive interpretation. Since "contaminated" and therefore "adulterated" foods "may", by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health and since frequently it could be plausibly argued that "such injurious nature cannot be adequately determined after such articles have entered interstate commerce" (section 12), this provision has an important bearing on section 12 covering licenses or permits and regulations by the Secretary, and strengthens the power of the Secretary to manage or "regulate" all manufacturers of such products and to close them up if they do not secure a license from him or if "any of the conditions of the permit have been violated" (section 12). It is difficult to anticipate fully how much trouble for manufacturers, advertisers, and publications may be implicitly contained in the provision that any food product is "adulterated" if any substance in it increases its bulk or weight, reduces its quality or strength, or creates a deceptive appearance; it clearly strikes at all "fillers", at all substances that may be held to be fillers even though they may be of value, such as limestone and other minerals which may furnish needed calcium and phosphorus in poultry or animal foods.

The provision (a) (1) and (2) corresponds pretty closely to section 10 and both are very dangerous to manufacturers of medicated foods, gums, candies, and the like in view of the definition of the term "food." But this could be remedied by defining the term "food" so that it would exclude from that category any substances for which medicinal or therapeutic claims are made. It does not appear to me, offhand, that (3), (5), or (6) under (a) of this section are objectionable.

It is impossible to anticipate how broad effect may be given to (1) and (2) under (b) of section 3 which provide that any food products shall be deemed "adulterated" (and therefore subject to all provisions relating to adulterated foods) "if any valuable constituent has been in whole or in part abstracted therefrom or if any substance has been substituted wholly or in part therefor"; for example, in the manufacture of ordinary white flour the wheat embryo (which is a rich vitamin source) and other parts of the wheat, such as its bran, are removed and each of those certainly constitutes a "valuable constituent" of wheat flour. It is frequently desirable to incorporate some other substance in a food product, such as something like cornstarch in salt to prevent it from lumping or caking, and such incorporated substance might, by departmental construction, be held to be "substituted."

Provision (b), (2) and (4) of section 3 should be omitted or changed and a provision forbidding the use of "fillers" should be included in their place. Then in section 2 (definitions) the term "filler" should be defined. It could be defined somewhat as follows:

"Any substance or ingredient in any food which is of no substantial nutritious value and serves no reasonably useful purpose or, if it does serve a reasonably useful purpose, is in a proportion unreasonably in excess of what would be sufficient and adequate for such purpose or purposes."

I am not sufficiently acquainted with the confectionery industry to appreciate whether provisions (c) and (d) of section 3 are subject to reasonable criticism.

Section 4: My observations on section 3 apply pretty much to section 4, which covers the adulteration of products falling within the category of drugs. But it is to be noted that they are not to be deemed adulterated simply because they "may" possibly be dangerous to health regardless of how taken or used (see

supra, sec. 2, and infra, sec. 10); to be brought within this provision it must appear that they "may" be dangerous to health when used according to the directions in the labeling. Since most drugs could be dangerous if misused, this is a wise limitation, because medicated foods and confectioneries are really medicines or drugs and bear, or should be required to bear, proper directions for their use, the term "food" should be so defined as to exclude medicated foods and confectioneries and foods and confectioneries for which therapeutic claims are made, so that they would come within section 4 instead of under (a) (2) of section 3 and under section 10.

Section 5: This section prescribes under what conditions cosmetics shall be deemed to be adulterated; under its provisions a cosmetic is not adulterated simply because it "may be injurious to the user." To be adulterated it must be such that "it is or may be injurious to the user under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual" or if it bears or contains any poisonous or deleterious ingredient prohibited or in excess of the limits of tolerance prescribed; this probably is as it should be. It properly takes into consideration directions for use of the product, just as such directions should be taken into consideration for medicated foods and confectioneries. (See, supra, secs. 2 and 4, and infra, sec. 10.)

Section 6: This section contains general provisions regarding misbranding that are applicable to all three kinds of products, foods, drugs and cosmetics.

The provision (a) that a product is misbranded if it carries any false statement or by ambiguity or "inference" creates even any misleading impression regarding any food, drug or cosmetic is not limited to the label or labels; it extends to the "labeling" which includes all matter that accompanies the product. This provision omits all such words as "fraudulent" and "intentional," so that honest belief, upon adequate investigation, of the truth of a statement or possible implication is no defense. Instead of "by ambiguity or inference creates" the provision should read "by ambiguity or implication may reasonably create ——." (The writer, label or labeling implies; the reader infers something that may or may not be implied. The manufacturer, packer or seller should not be held responsible for inferences that may be drawn unless they are reasonably implied.) Provision (a) is very broad and is very dangerous in view of the heavy penalties and penitentiary sentences provided in section 17 for selling in interstate commerce any "misbranded" product, and especially because of the indefiniteness of the term "false impression."

The second provision (b) of this section extends misbranding to a failure to state on the label (1) the name, place of business of the manufacturer, distributor, etc., and (2) an accurate statement of the quantity in terms of weight, measure or numerical count as prescribed by regulations of the Secretary, and provides that he can establish reasonable variations for small packages of foods and cosmetics (not drugs) and may make exceptions regarding canned foods labeled elsewhere than where packed. The third provision (c) is that such required information must be set out prominently and clearly on the label.

Section 7: This section relates to the misbranding of foods; it covers fill, name, imitation of other foods, identity, and quality. The last provision requires that if the product is represented as a food for which no definition of identity has been prescribed by regulations it is misbranded if its label fails to state the common or usual name of the food, if any, and the common or usual name of each ingredient in order of predominance by weight. This requirement for naming ingredients in order of weight is impractical. Finally, comes the customary "omnibus" provision authorizing the Secretary to prescribe by regulation any further information for the label as he may deem necessary to protect the public from deception, under which he could plausibly claim authority to require statements of all percentages and complete disclosure of formula; like the requirement for complete disclosure of the formulae on drug products (see comments under (e) of sec. 8), this would be unfortunate, as in the case of valuable trade secrets in the composition of perfectly harmless dressings, sauces, or in nice blends of seasoning and the like. The word "reasonable" or "reasonably" does not occur to put any limitation on an otherwise arbitrary discretion.

Section 8: In this section are the provisions prescribing what constitutes the misbranding of drug products. The first provision (a) (1) enacts that wherever the labeling (not label) mentions the name of any disease for which the product is not a "specific cure" although it is a "palliative" it must bear "in juxtaposition with such name and in letters of the same size and prominence," a statement that the product "is not a cure for such disease." This is unreasonable and is designed to hurt seriously the sale of package medicines which, although not "specified cures" are of real value as aids in the treatment of diseases. When it

is considered that there are only three or four drugs recognized as "specifics," the broad effect of this provision is more apparent. It would be much more reasonable and fair if this provision read: "If its labeling bears the name of any disease for which the drug is not a specific cure but is a palliative, unless the labeling, by appropriate language, clearly and fairly indicates or represents that the product is no more than a palliative or of value as an aid in the treatment of such disease." This would serve the proper purpose of any such provision and would not require such statements as "This product is not a cure for" such disease, immediately following every reference to the disease. Inasmuch as the labeling must be truthful and adequate, the only effect of this provision would be to seriously interfere with sales of package medicines.

The next provision (a) (2) would seriously discourage the development of any new products for the alleviation of human suffering. It provides that the labeling cannot bear any representation "directly or by ambiguity or inference" (implication?) concerning any effect of the product "which is contrary to the general agreement of medical opinion", even though the statement may be absolutely truthful. If the research department of some company manufacturing drug products, say Merck, Eli Lilly & Co., Squibb, or Parke-Davis & Co., should develop a new product for the successful treatment of a condition or disease which has theretofore been generally regarded as incurable, or has not been generally recognized as susceptible to beneficial treatment by that new drug or combination of drugs, how can it market the product? Must it first make a complete disclosure of the secret formula (so that all who wish can imitate or duplicate the product) and, then by an expensive course of education, first teach members of the medical, dental, and veterinary associations what it has learned only at the expense of patient, constructive research work? And here, as elsewhere in the act the words "by ambiguity or inference" are very dangerous and susceptible to broad extension by judicial or departmental interpretation. This provision would effectively remove incentive for expensive, valuable research work by private institutions and individuals. The term "general agreement of medical opinion" is altogether too indefinite for a statute which is, like this one, criminal.

Provision (b) of this section provides that if a drug product is for internal use by man and contains any quantity of any of certain named narcotic or hypnotic substances it shall be considered misbranded unless it bears the name of such substances and the quantity or proportion of them with the statement, in juxtaposition, "Warning, may be habit-forming." And it provides that the Secretary may designate as narcotics and hypnotics such other substances as he may find to possess those properties. Probably some such provision is advisable; I am not sufficiently familiar with the properties of drugs to express an opinion whether some of those named should be omitted or whether others should be included in the list.

The next provision (c) of section 8 provides that any product is misbranded if it contains any quantity of ethyl alcohol, ethyl ether, or chloroform, and fails to bear on its label a statement, as prescribed by the Secretary, of the quantity or proportion of such substance. This is probably proper in respect of drug products for use by human beings but I do not appreciate why this provision should, any more than the preceding provision (b), be applied to products for veterinary use. But, unlike that preceding provision which is limited to drug products "for internal use by man", this one extends to all drug products whether for external use only or for only veterinary use, as well as to those to be taken internally by human beings. I do not think that the application of this provision to drug products which, according to the labeling, are for external use only or only for veterinary use, serves any good purpose unless the named drugs exist in such high proportion that it might possibly be dangerous for a human being to make use of them. A statement of quantity or proportion means but little to the ordinary layman. Probably this provision would be better if it required that when any drug product contained any of those substances in a quantity or proportion which might make its use dangerous when used as might reasonably be expected or according to directions, the labeling must bear a statement of the percentage of those ingredients and of precautions to be taken in its use.

The next provision (d) of this section applies to all drug products not subject to provision (i) of this same section, that is to all except those represented as germicides, bactericides, disinfectants, or antiseptics for use on or in the human or animal body, for which that provision (i) makes other requirements regarding directions for use. Paragraph (d) provides that the labeling of all such other drug products must bear complete and explicit directions for use except as the Secretary may otherwise permit. That paragraph (i) is very objectionable and

it would be much better if paragraph (i) were omitted and if paragraph (d) simply provided that all drug products must contain reasonably complete and adequate directions for use.

The next provision of this section, paragraph (e) applies to all drug products not subject to the provisions of paragraph (b) of section 4, therefore to all drug products except such as are, or purport to be, something recognized in the United States Pharmacopœia, National Formulary or in any supplement thereto. Thus it hits all secret formulae. According to this provision "the name and quantity or proportion of each medicinal or physiologically active ingredient" must be given on the label. Here is the requirement for full, exact and explicit disclosure of all formulae.

In this connection I might quote one paragraph from the letter which I wrote on May 13 to Dr. Tugwell, Assistant Secretary of Agriculture, before this bill was introduced:

"I understand that there has been agitation for legislation requiring the complete formula for every drug product to be printed on the label. There is no justification for such requirement and it would be harmful. Such legislation is strongly advocated by the American Medical Association and the American Dental Association but those associations are not at all averse to governmental action that would injure the business of even ethical manufacturers of package medicines. I concede that when a product contains dangerous ingredients in quantities that might be harmful, it would be reasonable to require a statement of them on the label. There is no sufficient reason to require all ingredients to be listed, and to require publication of every formula would be absolutely vicious. There is very valuable property in many secret formulae of undoubted value. I do not think such legislation could be made to apply to existing products, because that would amount to depriving the owners of the formulae of property without due process of law. And for it to be enacted to apply to future products when a reasonable protection of the public does not require that, would simply injure the business of reputable manufacturers who now spend much in pure research work to develop valuable products, would discourage them from this constructive work and would make them common prey of trade pirates who would imitate their preparations and adopt identical statements of formulae. Legislation requiring statements of ingredients should go no further than is necessary to protect the public from physical injury. If a product is of no value or if its therapeutic claims are unwarranted it should be retired from the market by the Administration acting appropriately; but in a vain effort to prevent worthless products from appearing, legislation should not be enacted that would require the publication of all formulae and thereby injure and destroy legitimate business and deprive the public of the advantages flowing from the research and initiative of package-medicine manufacturers. There is a proper field for members of the American Medical Association and there is a proper and useful field for manufacturers of high-grade package medicines; neither should be permitted to force through legislation not required for the public welfare and designed to benefit that class of citizens to the injury of the other class and of the public."

A provision requiring full disclosure of all formulae for drug products on their labels would be:

(a) Unnecessary for the protection of the life, safety or health of the public—except possibly in case of products containing dangerous ingredients in quantities that might be harmful, and in such cases there would be no need for complete disclosure of the formulae and a statement regarding such ingredients and precautions to be taken would be sufficient;

(b) Useless because a statement of formula means nothing to the ordinary user of package medicines, and just so that doctors can prescribe such commercial products by formulae, instead of by trade name, is no sufficient reason for such a provision;

(c) Unjust because it would uselessly and without reasonable necessity wreck the package medicine industry—just for the benefit of a professional class; and

(d) Very unwise and impolitic because (1) I would deprive the public of many valuable package medicine products which are sufficiently meritorious to be commonly prescribed by doctors—just to compel people to go to a physician whenever there were need for such a preparation and to get it, or a prescription for it, from him for a fee; and (2) it would deprive the public of the undoubted benefits of private research on the part of commercial institutions since it would discourage such companies from that kind of expensive work by removing all incentive for it and compelling them to turn the fruits of their efforts, in the way of new and valuable formulae, over to trade pirates to be exploited at prices which woud be ruinous to the originators.

Besides being unwise, useless, and unnecessary, and to the manufacturers of package medicines absolutely destructive of their legitimate business and unjust, it would hurt publications which derive revenue from drug advertising very much. Why should a manufacturer spend thousands of dollars to create a demand for his package medicine product when every little human parasite who wished to do so could put out the identical product at no cost for development or advertising and hence at much lower price and could prove by the published formula that the two products were identical? It is apparent that the necessary result of such a law requiring full formula disclosure would be to reduce tremendously all drug advertising. Of course, that is a very real purpose of the provision for complete formula disclosure (and is the reason why the A.M.A. lobby even agitated for a requirement that every drug advertisement must carry a publication of the complete formula of the product and also for one forbidding the use of any trade name for a proprietary product). The most effective way to destroy the package medicine industry and to secure a sort of monopoly for the doctors, is to effectively stop the advertising on which that industry depends. Other provisions in the bill which would "discourage" the advertising of drug products in publications are one defining "false advertising" in such a way that even the most prudent and ethical advertiser could not reasonably expect not to inadvertently violate the law and go to the penitentiary (see sec. 9), those fixing grossly excessive penalties and inhuman penitentiary imprisonments to which he would be subjected whenever he violates it by disseminating any "false advertisement" regardless of honest and diligent effort to obey its provisions (see sec. 17 (a) 3 and 4, and (b) and (c) of sec. 17), and the provisions making the publishers, advertising agencies, and radio broadcast licensees subject to the same penalties for all such violations on the part of any of their advertisers (see sec. 17 (a) 3 and 4, (b), (c), and (d)). The bill surely and effectively "discourages" drug advertising.

As if the provision for complete formula disclosure were not enough, another "omnibus" provision is tacked on authorizing the Secretary to require any further information on the label as he may deem necessary to protect the public health, and here again there is no such limiting word as "reasonable" or "reasonably."

Paragraph (f) of section 8 simply provides that if the name of the product is the same as, or simulates a name recognized in the United States Pharmacopoeia or National Formulary or any supplement thereto, it shall be deemed misbranded unless it is packaged and labeled as prescribed therein. There is probably nothing objectionable about this provision.

Paragraph (g) of section 8 relates to products likely to deteriorate and provides that they must be packaged in such manner, and that the label must bear such statements for precautions, as the Secretary may prescribe for the protection of the public health and authorizes him to designate such drugs as he may find to be liable to deterioration, without any qualifying word or words to limit his authorization to reasonable findings or reasonable regulations.

Paragraph (h) provides that a drug product shall be deemed misbranded if its container is so made or shaped or filled as to mislead the purchaser or if it is an imitation of another drug or if it is offered for sale under the name of another drug. This last provision extends into the field of infringements of trade marks, trade names, and of unfair competition, and it would confer upon the Secretary jurisdiction in a broad field in which heretofore jurisdiction has been exercised only by the courts.

Paragraph (i) of section 8 is very serious and objectionable to manufacturers of drug products which can be designated as germicides, bactericides, disinfectants or antiseptics. It provides that any such product is misbranded if it is represented to be of such character and for any use on or within the human or animal body unless its labeling bears a statement of each such use and conspicuously "and in juxtaposition therewith, the method and duration of application necessary to kill all microorganism" with which it comes in contact when so used (unless it is represented as a germicide, bactericide, disinfectant, or antiseptic for only specific kinds of microorganisms and gives that information in respect of killing all of such specific organisms). Only germicides, bactericides, and disinfectants are supposed to kill micro-organisms; antiseptics may only inhibit the growth or multiplication of such organisms. I don't know how antiseptics are to be labeled and sold. If this becomes law it is going to be almost impossible to guarantee, as required, the conditions and time under which even germicides, bactericides, and disinfectants will kill 100 percent of the microorganisms with which they come in contact. One-hundred-percent efficiency should not be required of any medicine or drug product any more than any member of the American Medical Association should be required to have 100-percent success in treating disease cases. Some better, more practical and reasonable

provision should be written, such as that a drug product should not be represented, in labeling or advertising, to have germicidal, bactericidal, disinfectant or antiseptic properties unless, when used according to directions, it does in fact exercise such properties to an appreciable and reasonable extent that is of real benefit as an aid in the treatment of conditions for which the product is therein recommended, if any such provision is needed. But there is no sufficient reason for any provision referring specifically to germicides, bactericides, disinfectants and antiseptics; they are sufficiently covered by the other provisions of the bill applying to misbranding in general and to misbranding of drug products in particular. (See sec. 8 (d).)

Section 9: We come now to "false advertising" and paragraph (a) provides that any advertisement of any food, drug or cosmetic shall be deemed to be false if it is, in any particular, untrue or creates, either by ambiguity or "inference" (implication?), any misleading impression regarding the product advertised. What I have said under section 6 with reference to its first provision pertaining to labels and labeling is applicable to this one relating to advertising. (See sec. 6 (a).)

It should be noted that in order to amount to "false advertising," neither the manufacturer or advertiser, the publisher of the periodical or the radio broadcast licensee nor the advertising agent (with whose assistance the "false advertisement" is disseminated) need know or suspect or even have reasonable grounds to suppose that "in any particular it is untrue" or "by ambiguity of inference creates a misleading impression regarding" the product. All such words as "knowingly," fraudulently" and "intentionally" are omitted. The omission is intentional; that is clear from the fact that all such words are also omitted from section 17 (a) 3, and 4, which make "the dissemination of any false advertisement" by any means (and whether by manufacturer, wholeslaer, distributor, advertiser, publisher, radio station or advertising agency) a criminal act, and from section 17 (b) which fixes the penalties, fines up to $3,000 and imprisonment in the penitentiary up to 2 years, for "Any person who violates or causes to be violated any of the provisions of paragraph (a) of this section," and especially from (c) of section 17, which provides that "Notwithstanding the provisions of paragrah (b) of this section, in case of a willful offense the penalty shall be "imprisonment for not less than 6 months nor more than 3 years (a felony), or a fine of not less than $1,000 nor more than $10,000, or both such imprisonment and fine" for each such willful or intentional or knowing offense (with no discretion in the court to impose less than the prescribed minimum fine or imprisonment).

No matter how cautious or prudent a manufacturer or advertiser might be and regardless of all bona fide efforts on his part to scrupulously obey the law, he would be guilty and could be thrown into the penitentiary and heavily fined in any case where the Administration could succeed in convincing the jury that "by ambiguity or inference" any "misleading impression" even regarding the product could be drawn from the language of the advertisement. I say in all sincerity that no regular monthly advertiser could publish advertisements that could begin to pay for their cost and reasonably expect to stay out of the penitentiary.

And if the danger to the advertiser is great the risk of the publisher or radio broadcast licensee is greater. Because the advertiser can reasonably be expected to know much more about his own one drug product, what it will do and what it will not do, than such publisher or licensee can possibly know regarding all such advertisements "disseminated" in the pages of his publication or over his radio station; if the publisher or licensee knows or has reason to think that a particular advertisement is "in any particular" false or that it could "by ambiguity or inference (implication) create a misleading impression" he is guilty "of a willful offense" and subject to the heaviest penalties

In press releases officials of the Food and Drug Administration have a number of times referred to this omission of any requirement for intention or criminal intent (that is, knowledge of falsity) in the bill as the removing of one of the "jokers" of the old law. The wording of the existing law under which a manufacturer cannot be thrown into prison for an unintentional violation of the law may be a "joke" to those officials but is no joke to the manufacturer; to him it is a matter of his good name and liberty and the honor of his family. Manufacturers, advertisers, publishers, or radio broadcast licensees cannot but regard as tragic the provisions of this bill under which they could reasonably expect to be branded as criminals and even felons and thrown into the penitentiary without having had any reason to think they were committing a crime. This feature of the bill is too serious to them to be termed a "joker"; it is for them a "hook"—inserted to give the chief of the food, drug, and cosmetic control despotic power

in enforcing the law and "to discourage the public advertisement for sale in interstate commerce of drugs" (in the language of paragraph (c) of this same section) for the benefit of a small professional class.

The provisions of paragraph (b) of section 9 are analagous to the provisions (1) and (2) of paragraph (a) of section 8, but apply to any advertising (see definition of "advertisement" in sec. 2) instead of to labeling, and what I have said regarding paragraph (a) of section 8 applies to these provisions (1) and (2) of paragraph (b) of this section 9.

Consider the sales persuasion, "pulling power" or "punch", of an advertisement for a drug product which, although not an absolute "specific cure" for any disease, "is a palliative" (that is, of real value as an aid in the treatment of some disease condition—a product which is now often prescribed by physicians for such condition and is just as valuable as 99.9 percent of their prescriptions) if every time the advertisement mentioned the disease it had "to state with equal prominence and in immediate connection with such name the statement: "This product is not a cure for" such disease. Who could have thought of a more clever provision to kill drug advertising? That is what (1) of this paragraph (b) provides, and (2) extends to all advertisements of drug products the provision regarding labeling, that they are "false" if they represent, however truthfully, either "directly or by ambiguity or inference (implication?) anything concerning the effect of the product" which is contrary to the general (i.e., majority—not universal) agreement of medical opinion. (See sec. 8 (a) (1) and (2).) No one knows better than the medical men themselves how frequently the concensus of medical opinion has been, is, and will be false. The standard of truthfulness should be truth, and no man should be thrown into prison for the false opinion of others.

The next provision, paragraph (c) of section 9, prohibits the representation in any advertisement, "directly or by ambiguity or inference (implication?)" that any product has "any effect" in the treatment of a long list of specified diseases. A number of the diseases listed in this paragraph are, no doubt, recognized as incurable at the present time and no member of the American Medical Association can cure such diseases any more than any package medicine could cure them. But frequently doctors give or prescribe drugs or package medicines in such cases which give blessed relief to the sufferer and which, while not a specific or cure, are of sufficient assistance in the proper treatment of the incurable disease or in its proper care, to be worth while. Many members of the medical profession do not hesitate to accept fees for "treating" such diseases. Some of the diseases mentioned, such as measles or mumps, probably do not require anything more than palliative measures and proper nursing.

Certainly no package medicine should be permitted to be advertised or labeled as a specific, or cure, for any incurable disease nor should it be permitted to be represented as of any value as an aid in the treatment of any particular disease or condition unless it is of real value for the purpose. But under the provision of paragraph (a) of section 8, even if it is of value as a palliative, every time its labeling mentions any of the diseases listed in section 9 or mentions any other disease by name the label and labeling must "bear in juxtaposition with such name and in letters of the same size and prominence a statement that the drug is not a cure for such disease." That provision in section 8 ought to be enough, together with the analagous provision applying to the advertising of every drug product in paragraph (b) of this section 9, and together with the provision in paragraph (a) of section 6 and the provision in paragraph (a) of section 9 that an advertisement or label of a drug product shall be deemed false "if in any particular it is untrue, or by ambiguity or inference creates a misleading impression" regarding it. Those provisions should be sufficient. But this provision in paragraph (c) of section 9 provides that, even though a product is of very real value as an aid in the treatment or care of any of the named diseases, it cannot be advertised even as of "any effect in the treatment" of any of the diseases listed in that paragraph. It would forbid the advertisement of what is truthful. Have we come to this in legislation for the benefit of a professional class?

The effect of the provisions of this paragraph (c) of section 9 would clearly be to drum up business for members of the medical profession and advertising for the Journal of the American Medical Association, to drive people away from the druggists and to the doctors for prescriptions (which are very frequently for proprietary or package medicines). Where now the individual can get such package medicines from his druggist, the purpose of the paragraph is to make it necessary for him to first go to a physician, pay the physician his one or several dollars for the prescription and then pay the druggist a "prescription fee" for the same prod-

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uct with its label removed or dumped into a different container. The very language of this paragraph indicates these purposes; it states: "To discourage the public advertisement for sale in interstate commerce of drugs for diseases wherein self-medication may be expecially dangerous, or patently contrary to the interests of public health, any advertisement of a drug representing it * * * to have any effect * * *" etc. After listing the specific diseases the paragraph then goes on to provide that such advertisements shall not be deemed to be false if disseminated only to members of the medical and pharmacological professions or if they appear "in scientific periodicals" such as the Journal of the American Medical Association, so that that Journal may get the bulk of all drug advertising and doctors may know of such products to prescribe them for a fee but so that lay people will not know of them and cannot get them without paying the doctor a fee for a prescription and the druggist a fee for "filling" the "prescription." The very language, "especially dangerous" and "patently contrary to the interests of public health" carries an implication which Congress should hesitate to make, namely that all or most self-medication is dangerous" and "contrary to the interests of public health."

Lest that implication might not be readily grasped, might be overlooked, the paragraph ends up with a provision that it shall not be construed as indicating that self-medication is safe or efficacious even for any other diseases that are not mentioned and with another "omnibus" provision authorizing the Secretary to add any other diseases to, or remove diseases from, the list, with no words to limit him to a reasonable discretion.

Section 10: This is the section which, in view of the definition of "food" in section 2, would make it possible for the Secretary, without going into court, to completely wipe out any business in medicated gums, medicated candies, medicated breakfast foods (such as laxative candies and gums, aspirin gum and the like) by simply "finding" that a child might possibly eat or chew up a whole carton of the candy or gum or that a person, intent upon suicide, might do that and by then, after notice and hearing, issuing his regulation that such laxative drug or apirin cannot be added to gum, candy, or breakfast food. The easiest way to prevent this would be to change the definition of "food" so that it would exclude medicated substances to be eaten or drunk by humans. For further comment along this line see remarks above under section 2.

Section 11: This section authorizes the Secretary to promulgate definitions of identity and standards of quality and fill of container for food products upon notice and public hearing and to amend or repeal such definitions or standards after notice and public hearing. I am not sufficiently familiar with the food industry and its problems to detect the objectionable features, if any, of this section.

Section. 12: Although this bill does not make it mandatory for all manufacturers of food, drug, or cosmetic products to obtain a license from the Secretary if they are to continue in business, it confers upon him such broad power that he can as a practical matter require any such manufacturer to go out of business unless the manufacturer accepts a license from him upon almost any conditions he may see fit to fix regarding the operation of the plant. The Secretary need simply "find" that the distribution of any of the products may (not that they necessarily will or reasonably may) "by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health" and that such injurious nature cannot be "adequately" determined after such articles have entered interstate commerce; then he may "after notice and hearing" "make such regulations governing the conditions of manufacture, processing, or packing as he deems necessary to protect the public health" and require the manufacturers, processors, and packers "to hold a permit conditioned on compliance with such regulations." Since almost any food or drug product could possibly be injurious through mistakes in preparation or compounding and since the Secretary could decide that such mistakes could not be "adequately" determined or discovered after the product had left the plant, this provision practically gives him an unlimited discretion to license any food, drug, or cosmetic manufacturers.

The next paragraph (b) of this section authorizes him to issue such permits for any such periods of time as he may by regulation prescribe and to make any regulations regarding their issuance and renewal. He is authorized "to suspend immediately upon notice" any permit—that is without any warning, hearing, or opportunity for defense and without going into court; he can do this whenever he "finds" that any of the conditions of the permit have been violated", regardless of how slight the danger to health might be as a result of the violation of some condition of the permit. No manufacturer could afford to try to question or resist even an unreasonable regulation or condition. If, after his permit has been thus revoked, the manufacturer shipped one package he could be jailed for 1 year and fined $1,000 or both; if he shipped a second package he could be fined $3,000 and put in the penitentiary for 2 years and if the court found that he did this willfully or with knowledge that his permit had been revoked the court must imprison him for 6 months to 3 years or fine him from $1,000 to $10,000 or inflict both the fine and imprisonment. (See sec. 17, (b) and (c).)

Under these provisions of section 12 of this bill the Secretary could, by regulations and licenses or permits, control just about everything concerning personnel, formulas, methods of manufacture, equipment, plant and of working conditions because they could possibly affect health and because no manufacturer could afford to dispute his authority or try to resist.

The last paragraph (3) of section 12 provides that "any officer or employee designated by the Secretary shall have access to" any establishment operating under permit, "for the purpose of ascertaining whether or not the conditions of the permit are being complied with." Such access or permission to examine anything the inspector cares to investigate, had better not be denied because such denial is "ground for suspension of the permit."

Section 13: It is not only such manufacturers, processors or packers of food, drug or cosmetic products, as have been put under permits or licenses by the Secretary, that are subject to "inspection" by inspectors on the pay roll of the Food and Drug Administration or of the Department of Agriculture. The first paragraph (a) of section 13 provides that any officer or employee commissioned by the Secretary, if he first obtains the permission of the management, may enter any plant in which "food, drugs or cosmetics are manufactured, processed, packed or held for shipment" and may inspect it "and all equipment, methods, processes, finished and unfinished materials, containers and labels." The expression "after first obtaining permission of the" management is a "joker", intended to make the provisions read more innocently and to conceal, on casual reading, the full import and broad application of this provision. Because, to insure that the management will not withhold such permission, the second paragraph (b) provides that whenever such permission is withheld for an inspector to do any of those things the United States District Courts can issue an injunction, either temporary (that is, before any hearing) or permanent, to restrain the movement of any products from the plant into interstate commerce, until the permission is given, and to punish summarily for contempt any violation of such injunction.

Note that the Food and Drug Administration would have to provide out of its appropriations for the salaries of inspectors and expense of inspections under section 12 and section 13. Such inspections, conditions for licensing and cancellation of licenses or permits could be carried out in a most galling and oppressive fashion. Unless I entirely misunderstand human nature and the ways of bureaucrats and their desire to extend the operation of bureaucracic activities further than Congressional appropriations will usually permit, the powers under these two sections are very likely to be exercised in such a way that the average manufacturer will elect to "voluntarily" apply for the "Voluntary Inspection Service" cleverly provided for in section 22. This will relieve the administration of all expense in the matter of managing or "regulating" his business, so that it can, without increasing its expenses or need for heavy appropriations, enlarge its force of supervisory inspectors just as far as politics and bureaucratic policy or ambitions may dictate. (See section 22).

Section 14: By this section it is provided that any common carrier, railroad, express company, steamship or truck company shall upon request of any employee of the Department permit access to, and to copy, all records showing the movement in interstate commerce of the products of any food, drug or cosmetic manufacturer. It provides that it shall be unlawful for any such common carrier to fail to permit such access to and copying of records.

Section 15: Paragraph (a) of this section should be read in connection with section 23. Together they provide that the Secretary through any employees of his Department or through any food, drug, or health officer of any State, Territory, or county duly commissioned by him, may conduct examinations and investigations, like the Federal Trade Commission, anywhere in the United States and may compel the attendance of any witnesses and production of any documents just like that Commission and that, as in the case of the Federal Trade Commission, "The findings of fact by the Secretary shall be conclusive if in accordance with law", so as to make it impossible for the courts to reverse the decision of the Secretary or his underlings if there is any evidence by which their

findings could be sustained. For the full effect of section 23, sections 9 and 10 of the Federal Trade Commission Act, which is incorporated by reference, must be consulted. Among other things it provides that if anyone neglects or refuses to attend and to testify or to produce any documentary evidence in his power in obedience to the subpena he shall be punished by a fine of from $1,000 to $5,000 or imprisoned for not more than 1 year or both.

Section 15 (b) provides that the United States District Attorney must institute criminal or seizure actions upon demand of the Secretary, leaving no discretion to such district attorney; that this is the meaning of the provision is clear from the fact that it makes it the duty of the district attorney to so act when any State, Territory, or county health, food, or drug officer "presents evidence satisfactory to the United States attorney of any such violation."

The next paragraph (c) provides that the Secretary must give notice before reporting any violation for criminal prosecution (but not for seizure or injunction proceedings).

Section 16: Paragraph (a) provides that any article of food, drug, or cosmetic in interstate commerce that is either adulterated or misbranded or which has been manufactured, processed or packaged in a plant which did not hold a valid permit if required by the Secretary (under sec. 12) shall be subject to seizure either in a libel action or, if any designated employee of the Department has probable cause to belief that the product is so adulterated as to be imminently dangerous to health, just by order of that officer or employee. (Twice in this paragraph the bill refers to "libel of information"; if I am not mistaken, it should be "process of libel for condemnation.")

Paragraph (b) of section 16 provides for the payment of any judgment for damages against any officer, agent, or employee of the Department for wrongful seizure by the Government, "out of appropriations for the administration of this act." ("Those manufacturers who "voluntarily" apply for the voluntary inspection service must pay such fees as are fixed by the Secretary to cover the cost of the "service" "together with the reasonable cost of administration.") The purpose of the provisions of this paragraph is to make the employees and inspectors of the Department fearless and independent in ordering seizures providing "there is probable cause for the acts done" or providing they are done under the direction of the Secretary or under the direction of any employee of the Department whom he authorizes to direct such acts.

The next paragraph (c) simply provides that any "party to a condemnation proceeding" may obtain a representative sample of the article seized "before trial"; it should be noted that this does not provide that the manufacturer or owner may obtain such sample, unless and until he enters an appearance in the action and becomes a "party" thereto (so that the judgment of the court will be binding upon him and constitute res adjudicata as to him, which is not the case where he lets the case go by default.) Also note that it applies only to parties "to a condemnation proceeding", that is, to a libel action, and that it does not provide that a person prosecuted criminally for alleged misbranding or adulteration of a product, shall be permitted to obtain a sample of the lot of merchandise alleged to be adulterated or misbranded, in order adequately to prepare his defense.

Paragraph (d) contains the old provision that upon decree of condemnation of merchandise, the payment of the costs and the execution of a good and sufficient bond the court "may" direct the articles to be delivered to the owner thereof. The writer has had experience with this provision in a libel action in which over $10,000 worth of merchandise was seized and condemned for alleged misbranding. The Department did not contend that the product was without merit but it had taken exception to some of the wording on the label and to the trade name of the product and had had the large stock of merchandise seized without warning or opportunity to change the labeling to conform to its views. I went to Washington, conferred with officials of the Department and soon agreed upon changes in the wording which were perfectly satisfactory to the Department and to the owner and manufacturer. The owner and manufacturer then applied for the return of the merchandise under such a provision as this, agreeing to relabel the product according to the wishes of the Department and to post the bond for the faithful performance of its undertaking. Although the Department officials no longer contended that the name of the product was improper or constituted misbranding and although the wording of the old label which the Department alleged amounted to misbranding, had been incorporated on the label in good faith and without any intent to deceive, mislead, or defraud, the court refused (under a Department policy which it recognized and enforced as if it were law) to allow the property to be delivered to the manufacturer unless

it would admit every allegation of the libel (among other things unless it would admit that it had acted fraudulently and that the very name of the product—worth to the manufacturer at least $100,000—constituted misbranding).

Rather than make such untrue admissions reflecting upon its honor and integrity and that would destroy its property in the valuable and proper trade name of the product, the manufacturer naturally refused to comply with the unreasonable demand and, under the order of the United States district court, over $10,000 worth of valuable merchandise was ruthlessly destroyed. This case is not unique; it is typical of how this same provision in the existing law is administered by the courts under the influence of the Food and Drug Administration. One would have to be more optimistic than the writer to expect that this provision, that "the court may by order direct such article be delivered to the owner thereof", would be enforced with any greater consideration for manufacturers or owners than has been the analagous provision in the existing law. It should be provided that under similar conditions "the court shall by order direct" the return of the property.

The next two paragraphs (e) and (f) of section 16 provide that the proceedings shall conform to proceedings in admiralty cases, as at present, except that either party may demand trial by jury on any issue of fact, and that upon decree of condemnation the court costs and fees, storage and other expenses shall be taxed against the person, if any, intervening in the action as claimant.

Section 17: Paragraph (a) of section 17 makes any of the following acts criminal, whether committed by the manufacturer, wholesaler, advertiser, publisher, radio broadcast licensee, advertising agency, railroad or other common carrier or by anyone else: Shipping or receiving or delivering or offering to deliver, in interstate commerce any food, drug, or cosmetic product that is either adulterated (see secs. 3, 4, and 5) or misbranded (see secs. 6, 7, and 8); dissemination of any "false advertisement" by radio broadcast, United States mails, freight, express or in any other way, to induce either the purchase or sale of such products (see sec. 9); shipping in interstate commerce any food, drug, or cosmetic if the manufacturer, processor or packer does not hold a valid permit when so required by the Secretary (see sec. 12); the refusal of any common carrier to permit access to, or copying of, any record showing shipments of such products (see sec. 14).

This is followed by paragraph (b) which fixes the penalties for any of the criminal acts defined in the preceding paragraph: For the first, unintentional violation, imprisonment for not more than 1 year or a fine from $100 to $1,000, or both; for a second or subsequent, unintentional violation, imprisonment for not more than 2 years or a fine from $500 to $3,000 or both. The provision relating to the first unintentional offense declares that the act shall constitute a misdemeanor; the provision relating to the second and to each subsequent offense (and every shipment of a package would constitute a separate offense) does not state that it makes the second and subsequent offenses felonies, but it does because any crime which can be punished by death or imprisonment in the penitentiary for 1 year or more is a felony. That these provisions relate to unintentional violations is apparent from the deliberate omission of any word which, by judicial construction could import any knowledge, intention, fraud or criminal intent and from the following provision, in paragraph (c), which fixes the penalty for any "willful offense" and provides that for any such offense the heavier penalties shall be enforced "notwithstanding the provision of paragraph (b)" of the same section.

Paragraph (c) provides that in case of any intentional violation the penalty must be imprisonment from 6 months to 3 years (making the offense a felony) or fine from $1,000 to $10,000, or both.

In neither paragraph (b) nor paragraph (c) is the court allowed any discretion to impose only a nominal fine or less than the prescribed minimum penalties, under excusable or extenuating circumstances.

Paragraph (d) provides that no publisher, advertising agency, or radio station shall be prosecuted under the two preceding paragraphs of this section "for disseminating a false advertisement if, on request of an officer or employee designated by the Secretary, he furnishes the name and address of the person who contracted for" the advertisement or had it disseminated. Probably publishers would not normally be criminally prosecuted under the law but, whenever the Department wanted to punish a particular publisher it could do so by simply not requesting the information. Note how cleverly this is worded. The bill does not provide that the publisher or advertising agent shall not be convicted if he gives the informaion or except for refusal to give it; it provides that he shall not be prosecuted in those cases in which an officer or employee "designated by the Secretary" asks for the information and it is supplied. In most cases the infor-

mation is in the possession of the Department; in any case the Department could elect not to exempt the publisher or advertising agent from punishment. Probably the worst effect it would have would be to make the press too subservient to the Food and Drug Administration.

The practical effect of the legislation, if this bill is permitted to pass, will be to reduce very much the amount of space used by food, drug, and cosmetic advertisers and it will injure publishers almost as much as manufacturers in a pecuniary way, although for publisers it would not establish such an intolerable interference in the management of their plants. I think it would result in the Food, Drug and Cosmetic Administration dictating to a considerable extent the editorial policies of the press regarding the law, its enforcement, the activities of the Food, Drug and Cosemtic Control and with reference to package medicines and "self-medication."

Almost any publisher carrying food, drug, or cosmetic advertising in his pages and therefore knowing that any time any advertiser in his pages violated the law the Food and Drug Administration could subject him to the fines and imprisonments provided for in the bill would not be very likely to severely criticise the Administration or any bureaucratic excesses on its part and also would probably be quite responsive to "suggestions" from it regarding editorial policy concerning the law, package medicines, "self-medication" and the like.

I have heard that at least one publishers' trade association advised its members that publishers, licensees and agencies would not be punished criminally unless they withheld information regarding the identity of the advertiser. Section 17, (a) shows that publishers, radio broadcast licensees and advertising agencies are just as much subject to prosecution as their advertisers or clients. And this is made certain by section 17, (d) which defines the conditions under which the Administration can exempt them if it sees fit to do so.

Paragraph (e) provides that no dealer shall be prosecuted under paragraph (b) if he establishes a guaranty signed by the manufacturer or person within the United States from whom he received the product or advertising, by which the latter assumes full responsibility for any violation of the law, giving his name and address. The operation of this paragraph, if the bill becomes law, will probably move all dealers to require such guarantees from manufacturers of food, drug and cosmetic products.

The last paragraph of section 17 makes it a crime to forge, counterfeit, simulate or falsely represent without authority any marks, stamps, tags, labels or other identification devices authorized by the provisions of section 12 (for licenses) or 22 (department's seal of approval) and fixes the penalty at imprisonment for not more than one year or fine from $1,000 to $5,000 or both.

Section 18: This section provides that the acts, omissions or failures of an employee acting within the scope of his employment or office shall be deemed to be the acts, omissions, or failures of the employer as well as his own, (paragraph (a)), and that individual directors, officers or agents of a corporation or association shall be responsible for the violations of the corporation authorized, ordered or done, in whole or in part, by them, so that they can be jailed and fined (paragraph (b)).

Section 19: It is provided by section 19 that the "repetitious" shipping of either adulterated or misbranded food, drug or cosmetic products or the repetitious dissemination of false advertising by radio broadcasts, United States mails or otherwise can be enjoined by the district courts, by either temporary (with no preliminary hearing) or permanent injunction, that to secure such injunction it shall not be necessary for the Government to show any intention on the part of the defendant to continue such acts and that any violation of such injunction may be summarily tried and punished by the Court as a contempt and arrest can be made anywhere in the United States. Probably some such provision to prevent "repetitious" violations, whether by injunction as provided in this section of the bill or by a cease and desist order issued by the Secretary after proper notice and hearing, is advisable. The present method of attempting to discourage such repetitious acts by multiple or successive seizures as provided for in section 16, is clumsy, expensive and not expeditious or effective. Provision for informal conferences with possibility for cease and desist orders would do more than anything else towards adequately empowering the Food and Drug Administration to really clean up labels, labeling and advertising of food, drug and cosmetic products in the most efficient manner, smoothly, expeditiously, with sufficient protection to the public and without undue hardship or expense to the manufacturer, distributor, dealer or advertiser. With such a provision no provision for criminal prosecution, except for intentional violations of the law, should be necessary; nor would there be need for provisions for the clumsy, expensive and

inefficient procedure by seizure in libel actions (see section 16), except where products imminently dangerous to human life have found their way into interstate commerce. In this connection I quote from a letter which I wrote on May 13, 1933, to Assistant Secretary of Agriculture Rexford G. Tugwell, upon the request of an official of the Department of Agriculture (which letter was never acknowledged by Professor Tugwell or by anyone for the Department). In that letter I wrote:

"I come now to a suggestion which, so far as I know, is original and which I think, and believe you will think, is unselfish and constructive. I think the present set-up for enforcing regulation of label claims, standards of products, and advertising representations is clumsy, unwieldy, inconvenient, inadequate, and too expensive as well as unduly harmful to legitimate business. The method of suppressing unwarranted label claims and forcing the removal of substandard products from the market by seizure in libel actions is not sufficiently direct. The distribution of enforcement powers between the Food and Drug Administration and the Federal Trade Commission is senseless and unsatisfactory; all of the regulatory power in the food and drug field should be bested in the Food and Drug Administration. The injurious publicity that attends governmental action before the manufacturer or advertiser has been given a fair trial and found guilty is unnecessary, un-American, and unfair. My suggestion is that all regulatory power over food and drug products, labels and collateral advertising be vested in the Secretary of Agriculture and administered by the Food and Drug Administration; that when the administration has reason to believe that a product, its trade name, label claims or collateral advertising is unwarranted it should first, except in cases where danger to human life is involved, be compelled to summon the manufacturer or advertiser to appear informally for a discussion of the matter in an effort to secure voluntary change or withdrawal of product, name, label claims, or advertising statements, before taking any other regulatory action; that only in event such informal action fails or the manufacturer or advertiser fails to appear, a formal citation should issue commanding him to appear at a time and place certain to show cause why a cease and desist order should not issue commanding him to discontinue the product, name, label or advertising statement, and an appropriate complaint should be served upon him detailing the alleged violation of law; in reasonable time a hearing should be had, and the complaint either dismissed or a proper cease and desist order entered; of course there would have to be the opportunity of appeal to the courts which would be empowered to affirm or set aside a cease and desist order; at no stage of the proceedings until a cease and desist order is actually entered (except where danger to human life exists or where there is reason to believe the manufacturer or advertiser is acting fraudulently or in intentional violation of the law) should any publicity be given because the manufacturer or advertiser has not been found, after fair trial, to be guilty. The cease and desist order should be enforcible by penalties. I think this procedure would be about as direct, expeditious, and effective, with the minimum hardship to reputable manufacturers and advertisers, as any that has been proposed."

I still entertain the views expressed in that letter.

Section 20: This is the only section in the bill under which powers would be vested not comletely in the Secretary of Agriculture and his Department. This section pertains only to the importation into the United States of food, drug, or cosmetic products and to products so imported. (Under the existing law regulations are issued, at least theoretically, jointly by the Secretaries of Agriculture, of Commerce and of the Treasury.) The only exception in this bill is (see Sec. 23 (a)) that the Secretary of the Treasury shall join with the Secretary of Agriculture in issuing regulations under this Section 20, and shall cooperate in the administration of this section. I do not appreciate that there is anything objectionable about this section and I think that it is proper to vest in the Secretary of Agriculture full authority and responsibility for the administration of the law except as otherwise provided in this Section 20 and in Section 23 (a).

Section 21: This section authorizes the existing "legal blackmail" by which the Department distributes at public expense and all over the country reports of seizures (before any trial, opportunity for defense or judicial finding) which are frequently very damaging to the manufacturers whose names and products are mentioned. Worse, under the provisions of this section the Secretary can publish any "such information regarding any food, drug, or cosmetic as he deems necessary in the interests of public health and for the protection of the consumer against fraud." This can be done without any conviction, hearing or opportunity for defense and only the Secretary is the judge regarding what information shall be distributed and the frequency and extent of such distributions at public

expense. There would be nothing to prevent him from "deeming" information to be in the interests of public health or for the protection of consumers against fraud although it would be of little or no interest except "to discourage self-medication" or to otherwise "educate the public" up to calling in their physicians and veterinatians more frequently, to point out the "dangers" in the use of package medicines or to otherwise injure the package medicine industry.

Section 22 provides for the voluntary inspection service. Under its provisions the Secretary may, upon "voluntary" application of any manufacturer or packer of foods, drugs, or cosmetics, appoint "supervisory inspectors", to examine and inspect all premises, equipment, methods, materials, containers, and labels used by the manufacturer or packer. Here, then, is the bait to induce manufacturers to be hooked; if, and so long as, everything is found to conform to the provisions of this bill and to all "regulations", a manufacturer may be authorized to attach some kind of seal of approval of the Department on this product.

Under the practical operations of the law it probably will become advisable for every manufacturer of food, drug, or cosmetic products "voluntarily" to apply for this "service."

Of course, it will require thousands of "supervisory inspectors" to inspect and regulate all of the plants; the Department could not hope to get sufficient appropriations to enable it to support such a host of taxeaters. So point number one (of the two-pointed hook) is that the manufacturer shall pay fees to be fixed by regulations "in such amount as to cover the cost of the supervisory inspection and examination, together with the reasonable costs of administration." The other point of the hook is that the concern will practically pass under the management of the Food and Drug Administration regarding all matters of plant, personnel, equipment, formulae, methods, and operation.

I don't think there is any doubt but that, if the bill becomes law, the Department will push the expense of inspection off on the manufacturers by making it very advisable that they voluntarily apply for this service. They will get inspection anyhow, under the licensing provision (sec. 12) or under the factory-inspection provision (sec. 13), and the "supervisory inspectors" under the "Voluntary Inspection Service" will probably be much more reasonable fellows and much easier to satisfy than the inspectors sent out to "noncooperating" manufacturers, under those other two sections and at the expense of the Food and Drug Administration.

Under this section, and by a rigid or ruthless enforcement of sections 12 and 13 which can drive most manufacturers of food, drug, and cosmetic products to "voluntarily" come under section 22, the administration can put over a gigantic plan for the management and control of those concerns and at the manufacturers' expense.

If this bill becomes law the chief of the food, drug, and cosmetic control will become a powerful man with an army of underlings and will be tsar of the food, drug, and cosmetic industries. He will be treated with deference and regarded with fear and trembling by them and by all publications that carry food, drug, or cosmetic advertising and by the radio industry. Managing, supervising, or regulating concerns that now do a business running into the billions of dollars annually, he should then be entitled to a raise and to get a big salary. He will be able to pass out lots of patronage for the political party in power. Probably the concerns that exist only at his will, or which he could effectively put out of business, will be willing to make "voluntary" and substantial contributions to the campaign fund of the political party represented by him or by his Secretary of Agriculture; it will take only the tactful suggestion of the supervisory inspector in charge of the particular plant that it has been "put down" for $1,000 or $10,000, as the case may be.

I think that this section 22 is one of the cleverest in the whole bill. Officials of the Food and Drug Administration realize that it would be impossible to get sufficient appropriations from Congress to support the whole army of inspectors that they would like to have under them and that would be necessary in order to control and manage all the food, drug, and cosmetic plants of the country as they want to manage and control them. So this plan to get the effective management of the plants and at the same time make the manufacturers pay the entire load was devised.

Section 23: As broad as his powers are that are explicitly conferred upon him by other provisions of this bill, paragraph (a) of section 23 vests in the Secretary authority to prescribe any regulations he may deem necessary for the efficient enforcement of the law and provides that his regulations regarding notice and conduct of hearings shall have the force and effect of law. It provides that his regulations shall be promulgated in such manner, and shall take effect, as

he shall determine. No one can foresee how far he might be able to go under this extensive grant of power.

I have commented above (sec. 15) on the other two paragraphs (b) and (c) of this section.

Section 24: For additional "teeth" in the bill, this section provides: "A right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this act."

Section 25: By this section it is provided that if any provision of the act is declared unconstitutional or its applicability to any person or circumstance held invalid, the constitutionality of the remainder of the act and its applicability to other persons or circumstances shall not be affected thereby.

Section 26: Paragraph (a) provides that the act shall take effect 6 months after the date of approval and that until that time the existing law shall remain in force. But it provides that during the 6 month interval the secretary can conduct hearings and promulgate regulations, definitions and standards under the new act, which shall become effective when the act goes into operation.

Paragraph (b) of this section provides that this act shall not modify or repeal any of certain other acts and that it shall be held to be in addition to their provisions. Those other laws are: The Tea Import Act, approved March 2, 1897 (U.S.C., title 21, secs. 41–50); the Virus Act, approved March 4, 1913 (U.S.C., title 21, secs. 151–158); the United States Grain Standards Act, approved August 11, 1916 (U.S.C., title 7, secs. 70–87); the Insecticide Act, approved April 26, 1910 (U.S.C., title 7, secs. 121–134); the Import Milk Act, approved February 13, 1927 (U.S.C., title 21, secs. 141–149); the Caustic Poison Act, approved March 4, 1927 (U.S.C., title 15, secs. 401–411); the Virus, Serum, Toxin, and Antitoxin Act, approved July 1, 1902 (U.S.C., title 42, secs. 141–148).

The CHAIRMAN. Thank you. We will now call on Mr. Carson P. Frailey, president of the National Drug Trade Conference.

Mr. FRAILEY. I offer for the record the amendment suggested by Dr. Beal, and which was handed up a few moments ago. I should like to request that this be incorporated in the stenographic record so that it may form a part of Dr. Beal's remarks in the record.

The CHAIRMAN. It is already in the record; it has already been given to the reporter. It will appear in the record.

Mr. FRAILEY. Thank you.

Thereupon, at 1:15 p.m., the committee recessed to reassemble at 2 p.m.

AFTER RECESS

The committee met at the expiration of the recess, at 2 p.m., Senator Copeland presiding.

Senator COPELAND. The hearing will come to order. I assume that there are others here who are willing to file briefs instead of making statements. I do not want you to feel that by making this suggestion the committee is desirous of omitting anything from the record that you would care to have in it, but may I say again that we are simply making a record here, and you will be surprised how much these records are used. When it comes to debate, if there are some Members of Congress who are in opposition they get the argument out of the record; so you need not feel at all that the force of your suggestions will be lost simply by reason of having a brief printed instead of a verbal statement before the committee.

I am glad that the witnesses have borne in mind that the purpose of this bill is not primarily to control industry. The purpose of the bill is to protect the public, to protect the mothers and the children, to protect the citizens; and the fact that regulation is needed is not because the reputable concerns are unwilling to conform to high standards; it is because there are those in the country who are exploiting the public and desirous of imposing their products upon the public for gain. So that is why we have a bill before us at all;

it is that the public may be better protected against the unscrupulous than it is at present. I also realize that there are defects in this bill, but this is the bill as it was handed to us. When I say "us," I mean to you and to me.

Now, I assume that there are going to be amendments made to this bill. There are certain amendments which certainly, so far as I am concerned, I shall insist upon, and as one member of the committee will do all I can to gain the consent of the committee to the inclusion of such amendments. You have presented other amendments. Every amendment presented will be given consideration.

Is there anybody at this meeting who desires to present a brief instead of making a statement, or are all such briefs now in our hands?

We have a 5-minute speaker, Mr. Ray C. Schlotterer, of the New York Board of Trade.

STATEMENT OF RAY C. SCHLOTTERER, NEW YORK BOARD OF TRADE, NEW YORK CITY, N.Y.

Mr. SCHLOTTERER. The New York Board of Trade was organized in 1876. It is the second oldest civic association in New York. It cooperated with Government officials at the time the Pure Food and Drugs Act was written in 1906. It believes that the present act only in minor details has been defective, and a complete revision is uncalled for and unnecessary. It opposes the present Tugwell bill because it is anti-N.R.A.

Senator COPELAND. Now just a moment about that. Why is it anti-N.R.A.?

Mr. SCHLOTTERER. I will tell you about that in just a minute, Senator Copeland.

Senator COPELAND. All right.

Mr. SCHLOTTERER. No one will find fault with the underlying principles of this legislation, but is there a public demand for this measure at this time? A nation going through the throes of recovery needs a consideration of those problems connected with a revival; these are labor problems, monetary problems, and fiscal problems.

Recovery must be given first consideration and we do not believe that proper study on a subject as complete and as important as the writing of the new Pure Food and Drugs Act will be possible in the coming session of Congress. We have made a study of the effects of this legislation on industry. The passage of this bill affects the employment approximately of 1,775,000 people. The value of the products involved amounts approximately to 17 billion dollars. For this reason we believe that this legislation is anti-N.R.A., both from the standpoint of employment involved, as well as defeating the principles of the N.I.R.A., which is a partnership between government and industry, through the presentation of codes.

How does the public feel at this time on this proposed legislation? A survey was made, asking 100 chambers of commerce if there has been a public demand for a change in the existing act. Sixty replies have been received to date. Fifty-five report that there is no demand at this time.

Senator COPELAND. I wish to read into the record at this time some of these letters which I have received. They are as follows:

BOSTON CHAMBER OF COMMERCE,
Boston, Mass.

In reply to your communications relative to the proposed changes in the Pure Food and Drugs Act, please let me say that while a great deal of interest has been expressed locally in the proposed Tugwell bill I do not think that we can honestly say that any demand for this legislation has manifested itself in this vicinity up to the present.

JAMES H. WALSH,
Manager Bureau of Commercial and Industrial Affairs.

THE CHICAGO ASSOCIATION OF COMMERCE,
Chicago, Ill.

While we have not had occasion to survey by questionnaire the many thousand business concerns located in our community, I think it fair to say that so far as the ordinary sources of information are concerned, such as letters, calls at our headquarters, articles in the press, resolutions of business and civic groups, etc., we have not been aware that there was any demand for a change in the act.

We assume that your survey has to do with legislation now pending before Congress said to be sponsored by Prof. Rexford G. Tugwell, Assistant Secretary of Agriculture, and which, if enacted, would give unlimited powers to the Department of Agriculture with reference to preventing the manufacture, shipment, and sale of foods, drugs, and cosmetics.

LOUIS A. DUMOND,
Manager Industrial Department.

DES MOINES CHAMBER OF COMMERCE,
Des Moines, Iowa.

We find that there is no demand on the part of the public for a change in the existing Federal Food and Drugs Act. There have been no flagrant violations out here that we know of. I take it that your letter is written on account of the so-called "Tugwell bill" which is not in favor generally here. The consensus of opinion by those familiar with the bill is that it is too drastic and will defeat the very purpose for which it is intended. An amendment covering radio and other advertising to prevent false and fraudulent claims and to do away with inferior products that do no specific good or may be harmful, seems to be agreeable.

Local manufacturers are in full sympathy with the efforts of N.R.A. and A.A.A. but are holding down stock and curtailing advertising expenditures owing to the uncertainty of the bills pending.

Our manufacturers feel that the propaganda favoring the bill seems to come from the Department only. The public seems to think that it is an expression of the Bureau's desire for power rather than of what is needed. Any radical changes at this time would tend to cause greater uncertainty just when confidence is renewed. We have a large number of cosmetic and medicine manufacturers that would be seriously affected by such a bill.

JOHN D. ADAMS, *General Secretary.*

WASHINGTON MERCHANTS ASSOCIATION,
Seattle, Wash.

Your letter to the Seattle Chamber of Commerce has been referred to me.

Representing over 2,000 retail grocers in the State of Washington, I can say that our association has never had any request for changes in the existing Federal Food and Drugs Act. We have talked over the general provisions of the Copeland plan and view it with considerable alarm as it is loaded with dynamite and could be very destructive in our present trade set-up.

We believe that this is not the time to introduce radical changes in connection with the standards of food and drugs. We are all trying to coordinate the various factors of industry to meet new-trade agreements and if there is any merit in the proposed legislation, it should be taken up only after our present decks are cleared for action.

W. J. HINDLEY, *Manager.*

PORTLAND CHAMBER OF COMMERCE,
Portland, Oreg.

Subject. Is there a demand on the part of the public for a change in the existing Federal Food and Drugs Act?

Report. If the general public here is desirous of changes in the Federal Food and Drugs Act, that desire has not found noticeable expression. It is probably true of this subject, as of many other, that in the absence of a local campaign for or against change in the act, the general public would not be sufficiently aroused to express its views.

Northwest Canners Association. The canning industry believes that labels should show clearly whether the contents of the can, when considered as food, are good or bad. But the industry does not believe that the labels should be made to show whether the contents of the can are first, second, third, etc., grade. To illustrate: One of the best known, best selling, and most wholesome brands of food on the Pacific coast—a brand selling at a good price and finding its way to the most discriminating tables, qualifies fully as "good" rather than "bad." But if the food sold under this brand were to be graded according to arbitrary, established rules, it might cease to classify as first grade, and might be made to take an even lower grading.

This executive does not fear the results of fair regulations of the food industry, but does deplore the tendency on the part of many of the subordinates of the Department to set themsevles up as "czars" and pass judgment on their own whims, rather than on the merits of the case.

Flour and cereals. An executive in this industry is aware of pending changes in the act, but is not aware of any special interest in the proposed changes on the part of the western flour and cereal manufacturers.

Retail drug trade. The secretary of the local association reports that the national association and local druggists feel that the existing act should not be changed. They regard a new law as likely to be oppressive to legitimate business.

FRANK M. BYAM, *Manager.*

THE CHAMBER OF COMMERCE,
Salt Lake City, Utah.

There is absolutely no demand on the part of the general public of the intermountain area concerning the activities of the Pure Food and Drugs Act.

The present existing laws are satisfactory and I am of the opinion a great deal of the agitation regarding the supervision of the food and drug allied industry, is coming from those who may have a personal interest in attempting to establish one more bureaucracy.

GUS P. BACKMAN, *Secretary.*

Mr. SCHLOTTERER. Gentlemen, I do feel, the board of trade feels, that this legislation is anti-N.R.A.

Senator COPELAND. Just a moment. I would like to know more specifically why this is against the N.R.A.

Mr. SCHLOTTERER. Senator Copeland, we have codes; the industries have presented codes.

Senator COPELAND. Are they permanent codes?

Mr. SCHLOTTERER. We do not know, sir. They are for 2 years. This survey was made at this time: "Is there a demand for a change in the present Food and Drugs Act at this time?" These letters, and others I have, prove that they would work against the so-called spirit of the N.R.A.

Senator COPELAND. Have you been here at these hearings?

Mr. SCHLOTTERER. I was not here yesterday.

Senator COPELAND. You are assuming, of course, in all your statements that this bill is to be enacted as it is written; and, perhaps, if I were to pass judgment upon the bill exactly as written, I might agree with you; but when you say there is no demand upon the part of the American people and the women of this country to have protection against fraudulent, misleading, and harmful substances, I do not think the board of trade is on solid ground.

Mr. SCHLOTTERER. Senator Copeland, the codes that have been presented——

Senator COPELAND. We hope there will be such a revival of industry that there will not be a need for the continuance of the codes. This is a temporary emergency well understood by everybody; but this is not an emergency measure in that sense; this is permanent control on the part of the Government for foods and drugs.

Mr. SCHLOTTERER. In my first statement I said we believed that the emergency problems, the emergency measures, should be considered at this time, and we do not feel that with the coming session of Congress, which will be filled with monetary measures, fiscal measures, and of all kinds and descriptions, that it is the time to consider the rewriting of a bill.

Senator COPELAND. What you mean is that we must spend all our time protecting the banks and the holders of securities and that sort of thing, and must give no thought in such time to the physical needs of the people.

Mr. SCHLOTTERER. I believe the recovery should be first.

Senator COPELAND. And then the physical recovery later. Do you believe that is the sentiment of the Board of Trade of New York?

Mr. SCHLOTTERER. Senator, we feel, and these letters here prove, that there is no demand on the part of the public for a change in the existing act.

Senator COPELAND. But you think there is a demand, do you, on the part of the public for the relief of the great bankers?

Mr. SCHLOTTERER. I know some people feel that they would like to get their money frozen in various banks. I know there are communities shouting that the reason business is not improving is because the banks are closed.

Senator COPELAND. You and I live in the same city. I do not know that I have ever seen you before.

Mr. SCHLOTTERER. Yes; you have.

Senator COPELAND. I am here to say that the people of New York City are anxious to be protected against harmful food and drugs and cosmetics.

Mr. SCHLOTTERER. There is no question about that. They certainly are. As I said in the very beginning, the New York Board of Trade finds no fault with the underlying principle of this suggestion.

Senator COPELAND. That is good. I hope you will leave it there, because I would not want the impression to prevail here that the great representative body of New York was opposed in principle to this measure.

Mr. SCHLOTTERER. But I did go on to say, is there a public demand for this measure at this time?

Senator COPELAND. What difference would it make if there is not a public demand, if there is a public need?

Mr. SCHLOTTERER. I wish to present what these various chambers of commerce have said about that question.

Senator COPELAND. We are glad to have them and we will include them in the record.

(The statements of the various chambers of commerce referred to are as follows:)

CHAMBER OF COMMERCE,
Trenton, N.J.

Know of no particular interest locally in proposed revision.

WALTER LOCHNER.

CHAMBER OF COMMERCE,
Allentown, Pa.

Frankly, I know of no demand on the part of the public for a change from the present Pure Food and Drugs Act. I believe firmly, however, that the general public is solidly behind the Federal Government in the administration of the act now in force which seems to give ample protection. Any lessening of this protection would be a serious mistake. On the other hand, as I said, I know of no demand in this territory for any change in the present law.

WINFIELD CLEARWATER, *Manager.*

LANCASTER CHAMBER OF COMMERCE,
Lancaster, Pa.

I made a number of contacts, including the local newspapers, and so far as I can learn, there have been no demands, no agitation nor any publicity locally, so far as the existing Federal Food and Drugs Act is concerned. We believe we have our ear to the ground in matters of public affairs and in case we should slip, certainly the newspapers should be familiar with what is going on. There just doesn't seem to be anyone, locally, interested in the subject.

L. W. NEWCOMER, *Secretary.*

UTICA CHAMBER OF COMMERCE,
Utica, N.Y.

Dr. Shaw in his official position, perhaps better than anyone else hereabouts, is qualified to discuss this subject intelligently, so far as Utica is concerned.

GEORGE J. WINSLOW, *Secretary.*

NORRISTOWN CHAMBER OF COMMERCE,
Norristown, Pa.

None of our directors, all of whom represent a cross section of the business interests of our community, have learned of any tendency on the part of the public for a revision of the present law.

Frankly, one of our directors is very well posted on these so-called "Tugwell bills." After both sides of the matter were laid before the board the members were of the opinion that if these bills were considered favorably and passed they would work a decided hardship upon the manufacturers on account of the bureaucratic control which would be established and the extreme measures imposed by the requirements of the bills as now written.

Further, these bills would have a decided tendency to throw out of employment thousands of people now employed in legitimate business; also to increase prices tremendously upon such items as drugs, cosmetics and foodstuffs by placing the power of elimination in the hands of the Department of Agriculture. Certain firms could be forced out of business for no good reason, thereby retaining some favorite few.

Our board is entirely opposed to these bills as explained and there is absolutely no inclination nor has there been any on the part of the public for a revision of the present food laws.

EDWIN L. SEABROOK,
Executive Secretary.

HARRISBURG CHAMBER OF COMMERCE,
Harrisburg, Pa.

We have no evidence that there is any demand on the part of the public in this vicinity for change in existing Federal Food and Drug Acts.

R. W. CRIST, *Assistant Secretary.*

HARTFORD CHAMBER OF COMMERCE,
Hartford, Conn.

I have today personally talked with seven of the leaders and most reliable men in this community on this subject and there isn't one iota of diversion in the opinion that the present Food and Drug Act is a very good thing and of very great benefit. Any changes in its construction and administration should receive very careful consideration and deliberation before making such changes.

Relative to the possibility of making the administrative section of the Department of Agriculture the executive, the uniform expression has been that we should not encourage governmental supervision as the departments are not set up and manned for this kind of work; and the administration of such departments often goes beyond reason and injures the industry more than it benefits it. Everyone is strong for the establishment of rules governing the advertising so that advertisements will tell the truth and stop misleading the public. They felt that the public is educated largely by advertising and publicity and advantage should not be taken of those who are not fortunate enough to have the ability and education to understand the honest facts. There has been a great deal of good, constructive work done along these lines and every reasonable effort should be made to continue it.

C. B. WHITTLESEY,
Executive Vice President.

NEW HAVEN CHAMBER OF COMMERCE,
New Haven, Conn.

* * * Asking whether there is a demand on the part of the public for a change in the existing Federal Food and Drugs Act, I have no comment at the present time. There has been no great amount of publicity as yet on the proposed change and this may account for my lack of information.

J. F. FERGUSON, *Secretary.*

BENNINGTON CHAMBER OF COMMERCE,
Bennington, Vt.

There is no demand apparent to this organization for any present change in the Federal Food and Drugs Act. As an organization, we are most emphatically opposed to any Government set-up which unites under one head the executive, legislative, and judicial departments.

D. E. MOORE, *Secretary.*

CHAMBER OF COMMERCE,
Manchester, N.H.

Strengthening of laws having to do with public health is of paramount importance and deserves hearty cooperation of all agencies and every individual.

The best way to accomplish the desired results should be adopted. The form this plan should take is worthy of serious thought.

W. T. ANTHONY, *Secretary.*

SPRINGFIELD CHAMBER OF COMMERCE,
Springfield, Mass.

No demand by the local public for a change in the existing Federal Food and Drugs Act has come to our attention.

Doubtless it will be agreed that there are instances in which there is opportunity for desirable further safeguarding of the public's interests. It is believed, however, that there is no justification for the annihilation of important, and probably wholly innocent, industries representing a tremendous volume of commerce in an effort to curb a relatively small group of offenders.

Producers and public alike may well regard with apprehension any attempt to substitute bureaucratic opinion for fact, or the surrender of the control of great and legitimate enterprises to a governmental department.

F. J. HILLMAN, *Executive vice president.*

CHAMBER OF COMMERCE,
Portland, Maine.

As far as we have been able to learn, there has been no active agitation on the part of the public for a change in the present Pure Food and Drugs Act.

This of course is just an opinion, which we trust may be of help to you.

ADELBERT H. MERRILL,
Manager Research and Statistical Department.

FORT WORTH CHAMBER OF COMMERCE,
Fort Worth, Tex.

No demand on the part of the public has been brought to the attention of this organization calling for a change in the present Pure Food and Drugs Act.

JACK A. HOLT, *Manager.*

CHAMBER OF COMMERCE,
San Antonio, Tex.

We know of no great demand on the part of the public in this city for a change in the present Pure Food and Drugs Act.

PORTER A. WHALEY, *General Manager.*

RALEIGH CHAMBER OF COMMERCE,
Raleigh, N.C.

As far as we can ascertain there is no demand on the part of the public here for any change in the Pure Food and Drugs Act. If we should hear anything to the contrary we will be glad to communicate with you further.

H. B. BRANCH, *Secretary.*

CHARLOTTE CHAMBER OF COMMERCE,
Charlotte, N.C.

Your letter received. As far as we know there is no demand on the part of the public for a change in the present Pure Food and Drugs Act. This has not been called to our attention by any of our people.

C. O. KUESTER, *Business Manager.*

NORFOLK ASSOCIATION OF COMMERCE,
Norfolk, Va.

At this particular time I know of no such demand.

W. S. HARNEY, *Manager.*

MOBILE CHAMBER OF COMMERCE,
Mobile, Ala.

As far as I know, there is no demand whatever on the part of the public for any change in the Federal Food and Drugs Act. There have been no statements brought to my attention, nor have any communications been addressed to this organization, no committees have waited on me, and frankly I am of the opinion that the public is not asking for a change, or, to say the least, have not interested themselves to any noticeable extent.

O. M. PHILPS, *President.*

CHAMBER OF COMMERCE,
Roanoke, Va.

* * * asking for a statement as to whether or not there has been a local demand on the part of the public for a change in the existing Federal Food and Drugs Act, we wish to say that such a demand has never been brought to the attention of this Chamber nor have we heard of such demand through any other source.

B. F. MOOMAW, *Secretary.*

THE CHAMBER OF COMMERCE,
Topeka, Kans.

I am not acquainted with the popular demand of the public in regard to a change in the present Pure Food and Drugs Act.

MARK W. DREHMER, *Secretary.*

INDIANA DIVISION OF PUBLIC HEALTH,
Indianapolis, Ind.

I, myself, have heard no great clamor for a change in the Federal Drugs and Food Act. I would, however, not expect such, inasmuch as the public knows very little about the provisions of this act, although they are greatly affected by it.

THURMAN B. RICE, *M.D.*

FLINT CHAMBER OF COMMERCE,
Flint, Mich.

It is our honest opinion that there has been little or no interest locally in regard to demanding changes in the existing Federal Food and Drugs Act.

JOHN G. ROUTZON, *Manager.*

ST. LOUIS CHAMBER OF COMMERCE,
St. Louis, Mo.

We have not received any information from our members and at this time are not in position to make any comments to you as to their attitude. If we do receive such comments will be glad to forward them.

W. B. WEISENBURGER, *President.*

ILLINOIS MANUFACTURERS' ASSOCIATION,
Chicago, Ill.

Relative to your survey to determine whether there has been a demand on the part of the public for a change in the existing Federal Food and Drugs Act. No demand of this character has come to my attention. As a matter of fact there seems to be a disposition of opposition toward any change in the act at the present time.

JAMES L. DONNELLY.

GRAND RAPIDS ASSOCIATION OF COMMERCE,
Grand Rapids, Mich.

I believe I am stating the true sentiments of the public in this city and trade territory when I say that there is no demand or desire on the part of the public for a change in the existing Federal Food and Drugs Act.

Certainly there is no desire for a governmental administrative section of the Department of Agriculture or any other Federal department to act in a supervisory capacity concerning legislative and judicial matters regarding food, drugs, and allied industries that would involve control or censorship of advertising or selling by such a governmental department.

I am convinced that public sentiment in this section is practically unanimous in the feeling that the manufacture and distribution of foods and drugs are now and will be increasingly controlled and directed and censored by the existing laws and the existing and proposed codes of fair competition under the N.I.R.A.

Further, I am positive that it is the public sentiment that any uncertainty as to the possibility of further regulation or control of this type should be immediately ended by negative decision thereby giving business and industry some solid footing on which to climb to recovery because it is the general sentiment here that recovery is now being retarded to the extent that uncertainty exists as to provisions of proposed codes and interpretations of codes under N.I.R.A., in addition to the uncertainty which exists because of the manipulation of the dollar.

A. T. MCFADYEN, *Secretary.*

SPRINGFIELD CHAMBER OF COMMERCE,
Springfield, Ill.

So far as this office is concerned we have not been beseiged with requests or demands for us to take any action in this connection.

ROBERT B. IRWIN, *Manager.*

WHOLESALE MERCHANTS BUREAU,
Detroit, Mich.

We do not know of any demand on the part of the public for a change in this act. Only today I talked with many of the food and drug people who apparently are satisfied with the act as it is being enforced in Michigan.

With the public and dealers being satisfied with the present act, I believe we should hesitate before suggesting any changes.

E. E. PRINE, *Secretary.*

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THE COLUMBUS CHAMBER OF COMMERCE,
Columbus, Ohio.

We have no evidence whatever of any public sentiment in this community that has demanded a change in the existing laws. It is our belief that the present Food and Drugs Act has been proven amply adequate, and we believe that the proposed legislation would not regulate the proprietary drug and cosmetic industry, but would destroy the industry.

The druggists in this community, both wholesale and retail, are business men of high principle, substantial citizens of and believers in the welfare of the community, and can be relied upon to continue to conduct their businesses as in the past, ethically, fairly, and squarely, and with consideration for both their customers and their competitors.

FRED D. CONNELLEY,
Executive Director.

DAYTON CHAMBER OF COMMERCE,
Dayton, Ohio.

I know of no demand on the part of the public for a change in the existing Federal Food and Drugs Act.

With reference to public opinion of this community upon present Pure Food and Drugs Act, I think this is best reflected in the action just recently taken by the Dayton Druggists Association, when very strong resolutions were adopted opposing any change in the present laws.

I am sending you a copy of these resolutions, as clipped from the local press, for your information.

"Whereas, the Tugwell bill designed to control and regulate food, drugs, and cosmetics, is a vicious threat to the entire drug and toilet industry;

"And whereas if said bill as now written is passed, its provisions and enforcement will adversely affect the sales of wholesale and retail druggists to a disastrous extent;

"And whereas such control and regulation of said industry will cause new and increased unemployment to the extent of many thousands, vast losses in invested capital and trade rights, tremendous curtailment of advertising expenditure, and great loss of business to numerous allied industries;

"And whereas the ultimate power and control granted by the Tugwell bill to a 1-man power, is certain to result in denying the public the constitutional right of self-diagnosis and self-medication, so that the public will find it increasingly impossible to treat their common minor ailments, thus increasing the cost of medication tremendously;

"And whereas the Food and Drugs Act passed by Congress in 1906 is well understood and effective because of numerous interpretations by the courts of the land;

"And whereas, said act of 1906 could aptly be amended to include the cosmetic industry: Be it, therefore,

"*Resolved.* That the representatives of this association and the representatives of the allied industry present oppose the passage of the wholly unnecessary, radically un-American Tugwell bill, and that the president and secretary be and are hereby ordered to remit a copy of this resolution to each member of the house of representatives and to each member of the senate for the state of Ohio."

WAYNE G. LEE, *Managing Director.*

LINCOLN CHAMBER OF COMMERCE,
Lincoln, Nebr.

Inquiring whether there has been a demand on the part of the public for a change in existing Federal Food and Drugs Act, we have no information on the subject whatever.

W. S. WHITTEN, *Secretary.*

KALAMAZOO CHAMBER OF COMMERCE,
Kalamazoo, Mich.

I know of no business men's or general public demand for any change in the Pure Food and Drugs Act. I surmise there are a few who are interested in what Dr. Wylie started who may believe some of his work is being undermined.

My own belief is that it might be good for the consuming public and good for the ethical pharmaceutical houses if the flagrant cure-all claims of some of the popularly advertised preparations were restricted to the truth. If the retail code is administered right, it would seem that would be arrived at under the retail code.

EARL S. WEBER, *General Manager.*

TACOMA CHAMBER OF COMMERCE,
Tacoma, Wash.

We can only say that we have had no suggestions that a change of any kind be made in the present Federal Food and Drugs Act. * * * We have called up several people who would be interested in any such change and they report no agitation of any kind.

JAY W. MCCUNE, *Traffic Manager.*

OAKLAND CHAMBER OF COMMERCE,
Oakland, Calif.

Public opinion has been focused on this act, due to Federal Government activity in promoting the release of news reels and printed matter telling about some of the destructive and worthless compounds which are sold to the public as effective and beneficial drugs and foods. In addition to these activities, there have been published books, such as One Hundred Million Guinea Pigs, and others, that have aroused public interest in adequate and extensive control and censorship of commercial firms distributing foods and drugs.

We do not know that the solution of this problem lies in forming an administrative section of the Department of Agriculture for the control and censorship of advertising; however, we believe that some definite stop in this direction is essential.

JOSEPH M. PARKER, *General Manager.*

SACRAMENTO CHAMBER OF COMMERCE,
Sacramento, Calif.

California as you know is largely an agricultural State. Accordingly our food production interests are paramount. We are not likely in California to get the reaction from consumers and housewives leagues that you get in eastern States.

Our food interests generally are very much opposed to the new Food and Drugs Act on the grounds first that it vests unwarranted and arbitrary authority in the person of the Secretary of Agriculture; second that it attempts to regulate through a new definition for interstate commerce shipments of food products to other countries of the world; third that it sets up an unwarranted control over all forms of advertising; fourth that it vests in a regulatory and enforcement body, namely the Food and Drug Administration, power to fix standards for fruit products far above those necessary for the protection of the public health.

So far as we can determine, there has been no general demand in California for an act of this nature. On the contrary, we find that our food producing interests are satisfied with the present law.

A. S. DUDLEY, *Manager.*

CHAMBER OF COMMERCE,
Casper, Wyo.

I am attaching an editorial from this evening's issue of the Casper Tribune-Herald which covers the matter much more thoroughly than I could do in a letter, and I trust that it will be of some use to you.

Like all efforts of its kind, the propaganda campaign waged so industriously by Professor Tugwell in behalf of a measure to rewrite the National Pure Food and Drugs Act along drastic lines has served to emphasize defects and absurdities of the proposal as well as to point out its merits.

The result is that the measure is now facing its most severe challenge—that of being classed in some quarters as an anti NRA movement—and its significance is best realized by the fact that it will affect, directly and indirectly, about two million workers. This alone is enough to direct serious consideration to its provisions. * * * Because so many people are concerned, justice would dictate

that all phases of the measure and its effects be subjected to thorough analysis before the broad claims of the measure's author are accepted, even in part.

J. KENT KINNIBURGH, *Manager.*

PHOENIX CHAMBER OF COMMERCE,
Phoenix, Ariz.

So far as we know, there has been no pronounced demand on the part of the public here for a change in the present Federal Food and Drugs Act.

M. E. BEMIS, *Immigration Committee.*

DENVER CHAMBER OF COMMERCE,
Denver, Colo.

This chamber has had no occasion to formulate any views upon the subject and would not do so except upon specific request from the trade groups to be affected by such legislation.

G. E. COLLISSON,
Manager Denver Chamber of Commerce.

Senator COPELAND. The next speaker will be Mr. Lee H. Bristol, of Bristol-Myers Co.

STATEMENT OF LEE H. BRISTOL, VICE PRESIDENT OF THE BRISTOL-MYERS CO., NEW YORK CITY

Mr. BRISTOL. Mr. Chairman, I am vice president of the Bristol-Myers Co., New York City. I have for 3 years been successively president and chairman of the board of the Association of National Advertisers. As such I am interested in things relating to advertising, and my interest therein is a little broader than that specifically under the type of company that I represent.

Our company makes products that come under the scope and purview of the proposed legislation. For 26 years we have been acting and operating under the Pure Food and Drugs Act of 1906, with its amendments.

There is one point, Mr. Chairman, that I hoped to have this opportunity of making, because I believe these are the facts: That the chambers of horrors, so-called, illustrate the rat, the offensive minority, and it is an infinitesimal minority, but a dangerous one, in any organization of industry.

A great many other manufacturers here feel as we do, and we want to express ourselves as being in favor of anything in behalf of protecting the public.

There is one point that has been somewhat overlooked, I believe, by those who have addressed themselves to the subject. It is just this: The permanent, better type of manufacturer—not the medicine man, who sets up a stand at night and expects to fold up his stand in the morning and go away—is not over-consumer-conscious. He is probably more concerned with the consumer than the consumer is with himself. Our very life blood is involved, and the big manufacturer is interested in not only knowing the consumer but knowing more about him than he actually does himself.

We believe that the research sources used by reputable manufacturers are constantly studying for improvement in every phase in order to court and invite the reaction of the public. The type of company that is permanently in business is not interested in one sale and then no more. Their permanence in business is dependent upon faithful dealing with the consumers.

I just wanted to get that in the record; and, knowing you as I do, Senator Copeland, and knowing that you are interested in the fair-minded type of manufacturer, who is in the majority, I hated to have it thought that just exceptions alone were ruling. You will recall Henry Watterson's statement that it is rather difficult by legislative enactment to pin wings on human beings and make angels of them.

Senator COPELAND. The next witness is Northam Warren, of the Associated Manufacturers of Toilet Articles.

STATEMENT OF NORTHAM WARREN, REPRESENTING THE ASSOCIATED MANUFACTURERS OF TOILET ARTICLES

Mr. WARREN. Mr. Chairman, I am head of the Northam Warren Corporation, makers of Cutex and other toilet articles, and am here to represent the Associated Manufacturers of Toilet Articles. This is an old association, about 40 years old.

While we were originally organized for general trade purposes, it so happens that our activities in recent years have been largely those of policing the toilet goods industry and attempting to drive out the crooks, the scoundrels, the adventurers, and keep them out.

That explains why the members of our association are deeply sympathatic with the purposes of this bill, and with the fine work that has been done by Dr. Campbell in drafting the bill.

We do not consider it a perfect bill, and he does not claim it to be such; but we do believe that the purposes that he is aiming at are praiseworthy and in defense of the public health.

Believing that as we do, I would like to follow up what Mr. Bristol has just said and counteract in the record two instances brought up yesterday by Dr. Campbell. In his fairness he was kind enough to say that the Department does not know a great deal about cosmetics, never having had a great deal to do with them; but, nevertheless, I want to make it perfectly plain that the two instances of injurious products that be brought up do not represent any large part of the cosmetics of this country. I will give you the exact figures if you want me to be more specific.

Senator COPELAND. I am sure you are right about that; but it would be interesting if you would put the figures into the record.

Mr. WARREN. The turnover of cosmetics in the United States from figures I obtained this morning from the Department of Commerce are a little uncertain, depending on the groups of any cosmetics; but, generally speaking, the turnover of our industry is about $240,000,000; and the turnover of those two countries which were held up to public scorn yesterday, and whom we are as indignant over as any member of the public or Administration can be, represents exactly one one-hundredth of one percent of that amount. That is a comparatively minor percentage of offenders. We think they should be driven out. We think products of that kind should be stamped out, and we want to offer the intelligent and sympathetic cooperation of our industry to that end.

But I would like to have the record clear as to the composition of the men who make up this industry. We may represent the lighter

side of life as distinguished from the more serious side of drugs and foods; but, nevertheless, we have the same ideals that other gentlemen have who testified here, and we are trying to run a clean house; we are trying to build businesses that are permanent; and the best evidence that we are succeeding is that our association is 40 years old.

There is one other matter that was placed on the record. I do not want to reflect upon the professional standing or knowledge of the man that made the statement, but I am sure he will be fair enough to let me say this in rebuttal. He mentioned the fact that lard is put out in 4-ounce packages with some perfume and sold at $3 a jar. There are suits of clothes costing $150 and automobiles costing $10,000; and there are all sorts of high-priced luxuries for people who have money with which to buy them; but in our industry by far the largest part of the face cream does not contain lard unsuitable to the face, and it is sold in packages ranging from 10 to 35 cents per package. It is sold in every country on the face of the globe. That is why the American manufacturers of cosmetics have been successful.

When I entered this industry as a comparatively young man we stood fifth among the nations of the world in the production of this particular line of product. In the last 15 years we have outstripped them all.

Take products like face cream and face powder compacts. They outstrip in volume the products of any other nation, not even excepting France or England or Germany. We are rather proud of the fact that when our people go to other places on the globe they find our products there.

There is one thing that I would like to say, and that is that if this were to be a general public health measure; and, as one speaker suggested yesterday, it was to be brought within the scope of this bill, the protection of the public from all sorts of household appliances, such as silver polishes and cleaners, then I should say that cosmetics should rightly be included in the bill. My doubt about that is that I do not see where you are going to stop if you put cosmetics in, because they have not so much relation to public health as many other articles that are used in a person's daily life. Where are you going to draw the line between cosmetics, between furs, and between textiles, which constantly touch human skin; also cleaning compounds that are used by housewives every single day?

If the department is going to embark upon a program which includes everything that a person may need in the home, the American home, as a speaker said yesterday, then it was undertaking an enormous task; and somewhere in deference to the taxpayers that job has got to stop.

Senator COPELAND. You spoke about furs. As a matter of fact, the Public Health officials have had occasion to give consideration to furs. You will remember the possibility of the conveyance of anthrax from furs. So from time to time it has been necessary for public-health officials to go very far afield from the original purpose of health supervision.

Mr. WARREN. Thank you, Senator. And is it not true out of your experience as a Public Health official that paraphenyline-diamine has sometimes been used in fur dye, which renders the fur as dangerous as that product which makes people blind?

Senator COPELAND. To one who has sensitivity to that particular chemical, of course, there would be indeed more danger from the fur than from the occasional use of it as a hair dye. I can quite understand that.

Mr. WARREN. I am nearly through, and I just want to bring up two other questions that have arisen in our minds in connection with this bill.

In the first place, there is the difficulty of enforcing a rigid ban against some cosmetics that might be affected by this bill. We have just undertaken one social experiment and it has failed. Anything of this sort that attempts to legislate against people's private pet habits, the things that they like in their daily life, is apt to become a cropper. I want to show the difficulty that the Department may encounter. One of these instances is Russia. You all know of the experiment that is going on over there. The Government has been discouraging the use of luxuries. Every member of our association has some experience in that regard. We have a very large Polish business. Poland is a point of departure for toilet articles into Russia. Anybody going there will find what the conditions are. It is bootlegging.

Take another instance. Take Germany. Germany has been, through the press bureau, discouraging the use of cosmetics because of the fact that they do not seem to be associated with the serious purposes of the present regime. What is the result? I can testify that today the toilet articles business in Germany is excellent. The ban against cosmetics; not the ban but the discouraging propaganda put out, has only caused a determination on the part of the German women to use their favorite face powder or lipstick. So when we attempt to draw this too close we may interfere with people's private habits.

There is one other thought that will conclude the objections that have arisen in our minds, and that is the question of export. We need the world in the export of toilet articles. We see a good business in that respect. It is not only good business to have an American product above others in every field, but it also provides employment for hundreds of thousands of people.

We do not want to see, and I do not suppose it is within Dr. Campbell's plan, that this legislation shall be shaped in such a way that it is going to prevent the marketing of harmless products here which are still permitted in foreign countries, because the production in our line of business will then come to a stop. That is an important point from an industrial standpoint.

I still maintain that we have a sympathetic attitude toward the purposes of this bill, and on one point particularly, and that is advertising. I have a deep sympathy for the people who are nervous about the effects on advertising. Our association comprises some of the largest advertisers in America. I have figures about it, but I do not think I will put them in the record, because I do not want to have it broadcast just how much we do spend. Nevertheless, it is a substantial amount.

But our advertising dollar is worth a little less today than it was some time ago, because we have to compete with fraudulent, false, misleading claims in connection with nostrums. I am not saying this as any reflection upon the publishing interests; they are our

friends; but we do not believe that advertising as an economic force can ever reach its full value unless it is purified from some of the practices existing today. Pick up you favorite magazine and see if I am right.

If, in spite of these arguments, the committee still feels in its wisdom that cosmetics should be included within the scope of this legislation, then our association would like to see 2 or 3 simple amendments which will make it appear a little less hard in some of the administrative features and in some of the definitions upon our industry, without in any way affecting the high purposes which Dr. Campbell has in protecting the public health.

Mr. Chairman, may I ask our counsel, Mr. Hugo Mock, to address the committee now?

Senator COPELAND. You presented the matter in such good spirit, Mr. Warren, that we are glad to hear from Mr. Hugo Mock.

STATEMENT OF HUGO MOCK, REPRESENTING THE ASSOCIATED MANUFACTURERS OF TOILET ARTICLES

Mr. MOCK. Mr. Chairman, if it is possible I would like to inject a new note into this duscussion, and that is to lead it away a little from the characteristics of a debate in which the Government is trying to get as much as it can and the industry which we represent is trying to get as little as possible.

I think there are obvious defects in the bill. I have here, Senator Copeland, an interlineated copy of the bill with the suggested amendments which are referred to in the brief, and I will ask you to follow me for a moment on the interlineated copy.

When I say that the Government may get more than it wants, I will refer you specifically to the very broad definition of advertising on page 12. I studied that. I have not even any substitute for it because I could not work out any better language. I do not think the Government could only take advantage of the industry to try to stretch that unduly, but I think the language as it is is capable of almost any construction.

If I represented a defendant who was accused of anything under this act, the first thing I would do would be to plead that the Government of the United States came into court with unclean hands, because I would refer very simply to the poster advertising used by the United States. We have all seen these naval posters: "See the world"; "Join the Navy". And you see a beautiful poster picturing tropic seas, and an immaculately groomed officer with an immaculately groomed horse. Everything is lovely. That poster is certainly creating a misleading impression.

Senator COPELAND. I thought I was the only man in the United States who had been mad about those posters, for the very reason you have suggested.

Mr. MOCK. Those posters never show a gob swabbing a deck or sleeping in a hammock with the temperature around 100°, or anything like that.

Although I am in favor of this bill, I think the language should be corrected.

Now to our specific amendments. Dr. Beale yesterday objected to the wording of section 5, on page 6, and it was your own suggestion,

Senator Copeland, that before the word "user" there should be inserted the word "average." My own suggestion before I heard you speak was the word "ordinary." I do not know which is better; but I think if either the word "average" or the word "ordinary "is inserted there it would exclude the causes of hypersensitivity referred to yesterday and save a great deal of trouble.

Senator COPELAND. That is exactly what I had in mind, because paraphenyline-diamine is irritating, but to the average person no such evil symptom is presented.

Mr. MOCK. This association has been so rigorous, Senator, in its admission to membership that no one who uses paraphenyline-diamine has ever been admitted. I refer to the much more common causes of hypersensitivity. I think the word "ordinary" would cure that.

The bill suffers from the defects of trying to be three bills in one. It legislates for foods, for cosmetics and for drugs all at the same time. In general we have no objection to telling the customer what is in the package; but our articles are bought not only for their regular value; but for their esthetic use and for their use as beautifiers.

In the case of perfumes it is very difficult to put the contents on the labels. Sometimes 2 ounces of perfume are sold for $50, and they are sometimes sold for 10 cents.

In the case of lipsticks there would be no object in putting the contents on the package, because every lipstick, whether sold for 10 cents or $50, is of the same size. No lipstick is ever bought on account of quantity.

I ask that on page 7 an exemption be put in on cosmetics. Packages of 2 ounces or under shall be exempt from the provisions of this section.

Now, will you please turn to page 11, to the section which discusses the private formula class. Dr. Campbell said very well from his point of view that a man who is his own doctor is entitled to know what he is putting into his stomach. Now, this section does not refer to cosmetics specifically, but there are many cosmetics which are also drugs. In the definition of drugs, and in the definition of cosmetics, the term is used that those cosmetics shall not be mutually exclusive. But to be more specific, if Coty makes a shaving lotion and puts on that lotion, "Good for bleeding", that article at once becomes a drug as well as a cosmetic.

Now, under this section, since it is not made in accordance with any article in the pharmacopia, Coty would be compelled to put upon the label the actual physiological ingredients of that product. You would have a label filled with probably 20 scientific names, essential oils, synthetic drugs, alcohol, fixatives, and other things which furnish no information whatever to the consumer and would only suffice to give away a valuable trade secret to a competitor.

Now, that product, in the first place, is not for internal consumption. So that takes away one reason why the formula should be disclosed. That product is never prescribed by a physician. So I submit in behalf of the cosmetic manufacturers that either an exception be made in the case of cosmetics, or that that paragraph be stricken out.

Senator COPELAND. I have written in my book that you wish to have this omitted entirely, or certainly omitted as to cosmetics.

Mr. MOCK. Yes, sir.

Now, please turn to page 17. Section 12 contains the laudable provision, as in the Crab Meat Case cited yesterday by Dr. Campbell, that—

> whenever the Secretary finds that the distribution in interstate commerce of any class of food, drugs, or cosmetics may, by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health, and such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he is authorized, after notice and hearing, to make such regulations governing the conditions of manufacture—

and so forth.

Then you have this intrastate inspection of factories. Now that is very good, and we concur in that, but there is not any reason in the world why it should ever apply to cosmetics, and I think it is merely an inadvertance. It does not appear in section 13 of the act. In section 13 it says:

> In order adequately to regulate interstate commerce in food, drugs, and cosmetcis, and enforce the provisions of this act.

Now, cosmetics are not bacteria carriers. In fact, most of them destroy bacteria. There is not a thing you would ever find about conditions of health by going into a cosmetics factory; and I submit that a limitation should be put in section 13 so that that factory inspection could have the same limitation as section 12. That is only in cases where the public health is involved.

Now, I have just two more; and my last two points have to do with the general features of the act, as well as with cosmetic. There is one other person involved in this act besides the public and the Government, and that is the manufacturer, and very often the rival manufacturer. This publicity provided in section 21 of the act is a two-edged sword. I believe that that section should also be limited to cases of emergency involving the public health.

As Senator McNary said yesterday, a man is believed innocent until he is found guilty. Now, what under heaven is the purpose of advertising a seizure or a complaint against an article in interstate commerce if afterwards the complaint is withdrawn and the defendant is found not guilty? That not only is no protection to the public, but it is very often used, or could be used, by competitors very disadvantageously.

Senator COPELAND. Mr. Mock, you propose on page 18, in line 6, to insert the new language that you furnish, with the understanding that the addition or change should be made on the preceding page.

Mr. MOCK. That is right; and I propose, although it is not in my brief, that under "publicity" that that publicity should be limited to cases of emergency involving the public health.

Senator COPELAND. Where is this now?

Mr. MOCK. This is on page 28. It says:

> No seizure or complaint shall, however, be publicly reported until final judgment has been rendered in the case.

Now, there is one other item that I want to mention, and that is the case of penalties. Mr. Burke this morning made a very resonable plea for taking up minor violations of law in a friendly manner with the Department, and I think practically all manufacturers would be very glad to cooperate with the Department in correcting matters of labeling or matters of packaging. The penalties as provided in the act, I think, are for a serious infraction, for a willful infraction of the public health. I think they are too mild as a penalty. For minor misbranding they are much too severe.

I call your attention to this factor. The larger the company the more there is the mathematical certainty that at one time or another they will be guilty of some technical violation of the act. The number of grapefruit in a case may not be correctly stated. Bottles are now made by machine almost universally and they are not always uniform.

Senator COPELAND. Mr. Mock, if this suggestion made by the doctor this morning about minor offenses were adopted, the suggestions that you are making now would not need to be carried into effect, I assume?

Mr. MOCK. I would withdraw them, Senator.

In conclusion I just want to say this: I came here with a great deal of fear and trepidation, because I think it is a problem of tremendous complexity to draw a bill for three separate industries. The association that I represent has no pride of opinion. It will cooperate with you in this bill or any other bill, or in the amendment of the present bill.

In conclusion I just want to say this: I see no reason under heaven why, if you are not permitted to lie on the label or a package, you should be permitted all the lying you want in your advertising or over the radio, and I do not care whether the restrictions are put in this act or with the Federal Trade Commission or in any other way. I think anything that makes for cleaner advertising will help an industry and also the public.

Senator COPELAND. The next witness will be Mr. John S. Hall, representing the Flavoring Extract Manufacturers Association, and others.

STATEMENT OF JOHN S. HALL, 1261 FIRST NATIONAL BANK BUILDING, CHICAGO, REPRESENTING THE FLAVORING EXTRACT MANUFACTURERS ASSOCIATION OF THE UNITED STATES, THE NATIONAL ASSOCIATION OF MANUFACTURERS OF FRUIT AND FLAVORING SYRUPS, AND THE NATIONAL MANUFACTURERS OF SODA WATER FLAVORS

Mr. HALL. Mr. Chairman, the members of the Flavoring Extract Manufacturers Association of the United States consist of manufacturers engaged in the manufacture, production, preparation, packing, distribution, and sale of packaged food products, flavoring products, common household remedies, and patent and proprietary preparations for culinary purposes sold to the retail trade. The members of the National Association of Manufacturers of Fruit and Flavoring Syrups consist of manufacturers engaged in the manufacture, production, preparation, packing, distribution, and sale of crushed fruits, fruit, and flavoring syrups intended for use in the dairy, ice cream, confectionery, soda fountain, and still-beverage industries for further manufacturing purposes.

The members of the National Manufacturers of Soda Water Flavors consist of manufacturers engaged in the manufacture, production, preparation, packing, distribution, and sale of soda water flavors and concentrates intended for use in the still and carbonated beverage industries for further manufacturing purposes.

In the opinion of our members the food, drug, and cosmetic industry of the United States is threatened with the most revolutionary and confiscatory legislation ever imposed upon such an important and essential industry. The proposed revision of the Federal Food and Drugs Act of 1906 now before this honorable committee suggests that the American people abandon the reasonable regulatory policies under which the industry has thrived in this country.

The Constitution of the United States and the constitutions of the various States have well defined the right of sovereignty as the basic or organic principle of law, and from this source is derived the authority to enact, construe, administer, and enforce laws. The theory of our Government, National and State, has always been opposed to the granting of unlimited power to any officials. The legislative, judicial, and executive branches of our Government are all of limited and well-defined power. The legislative branch is empowered to enact laws. The judicial branch is clothed with power to interpret and administer all laws and to outline methods of enforcement. The executive branch has the authority to supervise, enforce, and execute all such laws. In order to prevent a conflict of the various authorities the courts have time and time again held that legislatures cannot delegate to officials, boards, and commissions blanket power to enact a law or to declare what the law shall be or grant unrestricted discretion in applying a law. The intended law must be complete in itself and designed to accomplish a general public purpose, and must expressly authorize designated officials to provide rules and regulations for its enforcement within definite valid limitations specifically set forth in the law and in accordance with the Constitution.

A number of the speakers yesterday referred to arguments presented in 1906 when the present law was adopted. It is well to direct the attention of this committee and the American industry to the profound wisdom exemplified by the author of the Federal Food and Drugs Act of 1906, which was known as the Heyburn Bill in the Senate. I quote Senator Heyburn (Cong. Rec. vol. 40, pt. 3, p. 2721):

> If there is anything that this bill, and especially that this section of it (sec. 4), does not provide, it is for the fixing of standards by anybody. If there is anything that is not provided for or permitted under this bill, it is that the Chief Chemist, or the Chief of the Bureau of Chemistry, shall have power to denounce anything under any circumstances or to place a ban upon anything, or, as I stated yesterday, to place the ban of disapproval upon anything. He is given no such power. He is simply the agent of the courts to gather testimony upon these questions for the purpose of being used at the trial in the court room and nowhere else. * * *
>
> This bill fixes no standard upon anything; it authorizes no officer to fix any standard. It provides that the courts, and the courts alone, may determine whether or not an article is contraband under the provisions of this act. The object in avoiding any possible construction that might be held to be fixing a standard was that the bill might never come to conflict with the pure food legislation of the various States. The States have established different standards, and they have a right to do so. Inasmuch as those standards vary, it would be impossible for an act of Congress, a general law, to avoid some conflict with some of those State laws if you should undertake to fix standards.

I again quote from page 2723 the following statement made by Senator Heyburn:

> I wish to have it understood that this bill does not permit the Chief Chemist of the Bureau of Chemistry to fix standards or to punish anybody, or to brand his goods as fraudulent, under any circumstances. It does not permit the Secretary of Agriculture to do so. It does not permit anyone except the court, after a trial by a jury, if the party shall appeal to that right, to brand the goods as being fraudulent or obnoxious to the provisions of this bill.

A vivid contrast will be apparent from a study of the foregoing principle and the tenor of the drastic amendments now contained in the proposed revision of the Federal Food and Drugs Act of 1906. A condition no less than confiscatory is threatened in the food, drug, and cosmetic industry if the tenets of the above legislation are carried into the enforcement of this new bill.

I propose to direct your attention to definitive interpretations of the various sections of this bill, and the manner in which it will affect the industries I represent:

Section 2 in part provides that only the Secretary of Agriculture shall have authority to promulgate legal definitions and standards for the words "food, drug and cosmetic", and the labeling and advertising thereof.

> SEC. 3. Adulteration of food.—A food shall be deemed to be adulterated (a) (1). If it is or may be dangerous to health. (2). If it bears or contains any added poisonous or added deleterious substances prohibited or in excess of the limit of tolerance prescribed.

Objection to the proviso "if it is" or "may be dangerous to health." No reasonable interpretaion provided, and the Secretary of Agriculture is sole arbiter of fact.

> SEC. 3. (b) (1). If any valuable constituent has been in whole or in part abstracted therefrom; or (2). If any substance has been mixed or packed therewith so as to increase its bulk, or weight, or reduce its quality or strength, or create a deceptive appearance.

Objection to language so broad and loose that it may be subject to harmful interpretation, especially the reference to "deceptive appearance."

> SEC. 4. Adulteration of drugs.—A drug shall be deemed to be adulterated (a): If it is or may be dangerous to health under the conditions of use prescribed in the labeling thereof.

Objection to the proviso "if it is" or "may be dangerous to health." No reasonable interpretation provided, and the Secretary is sole arbiter of fact.

> SEC. 4 (b) (1). If any valuable constituent has been in whole or in part abstracted therefrom (4) if any substance has been used or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or create a deceptive appearance.

Objection to the provision as set forth under section 3 (b) (1).

> SEC. 5. Adulteration of cosmetics.—A cosmetic shall be deemed to be adulterated (a) if it is or may be injurious to the user under condition of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

Objection to this provision as set forth under section 3 (a), and section 4 (a).

> SEC. 6. Misbranding, general.—A food, drug, or cosmetic shall be deemed to be misbranded (a) if its label is in any particular false, or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetic.

Objection to the provisions contained herein that the Secretary of Agriculture is arbiter of "inferences, amibguous or misleading impressions."

> SEC. 6 (b). If in package form it fails to bear a label containing (1) the name and place of business of the manufacturer, packer, seller, or distributor.

Objections to the "place of business of the manufacturer" requirement. A strict enforcement of this provision would result in sectional distinction, and un-American disparities.

SEC. 6 (c). If any word, statement, or other information supplied on the label to avoid adulteration or misbranding under any provisions of this act, is not prominently placed thereon in such manner as to be easily seen and in such terms as to be readily intelligible to the purchaser and user of such articles under customary conditions of purchase and use.

Objection: The Secretary of Agriculture is given sole power to determine if any word, statement, or other information is prominently placed in such a manner as to be readily seen, and in such terms as to be readily intelligible.

SEC. 7. Misbranding of foods.—A food shall be deemed to be misbranded (a) if its container is so made, formed, or filled as to mislead the purchaser.

Objection: The Secretary allocates to himself the exclusive right to delegate the manner in which all food products shall be packaged for sale.

Section 7 (a, f, and g) in part provides that food is to be deemed misbranded if such food is not defined in such terms as the regulations specify, or if it is represented as a food for sale for which no definition or identity has been prescribed by regulations, and if the label fails to bear among other things the name of each ingredient thereof in the order predominant by weight. Objection to the provisions contained herein that the Secretary of Agriculture has authority by regulation to require a complete formula disclosure of all food products. No provision is made for the manufacture and sale of food products under a distinctive name. It also excludes the right of manufacturers to sell food products under a distinctive name. This practice has been in effect for the past 25 years, and no serious objection nor harm has come to the consumers of such products by the privilege of establishing distinctive name products; on the contrary it has acted to their complete protection.

SEC. 9. False advertising: (a) An advertisement of a food, drug or cosmetic shall be deemed to be false if in any particular it is untrue or by ambiguity or inference creates a misleading impression regarding such food, drug or cosmetic. (b) An advertisement of a drug shall also be deemed to be false if it included the name of any disease for which the drug is not a specific cure, but is a palliative, and fails to state with equal prominence an immediate connection with such name that the drug is not a cure for such disease; or any representation directly or by ambiguity or inference concerning the effect of such drug.

Objection to the fact language used in the proposed provision is so ambiguous and provides such gross criminal sentences for even "misleading impressions" and the construction of what is proper advertising, labeling, etc., and what is not, all written in such a loose and broad fashion that it is completely confusing in view of the present American standards.

SEC. 10 (a). If the Secretary finds that the presence of an added poisonous or added deleterious substance in or on food or cosmetics is or may be injurious to health, taking into account other ways in which the consumer or user may partake of or be exposed to the same or other poisonous or deleterious substances, then the Secretary shall by regulations promulgated after notice and hearing prohibit such added substances in or on food or cosmetics, or establish tolerances limiting the amount therein or thereon, to such extent as he may deem necessary to prevent such injury to health.

Objection: The Secretary of Agriculture is solely authorized to determine what ingredients contained in food products shall be considered deleterious to health. A question of such broad nature and of such paramount importance to the public at large should hardly be left to one individual.

SEC. 11. The Secretary is hereby authorized to fix, establish, and promulgate definitions of identity and standards of quality and fill of container for any food. Whenever the Secretary deems that for the purposes of this act any such definition or standard should be established for any food, he shall give notice of a proposed definition or standard and of the time and place of a public hearing to be held thereon not less than 30 days after the date of such notice. After such public hearing the Secretary may fix, establish, and promulgate a definition or standard for such food. The definition or standard so promulgated shall become effective on a date fixed by the Secretary, which date shall not be prior to 90 days after its promulgation. Any such definition or standard may be amended or repealed after notice and hearing as hereinbefore provided, and if amended or repealed the amendment or repeal shall become effective in the manner and at the time hereinbefore provided.

Objection: The Secretary of Agriculture is not required under this provision to follow the recommendation of America's largest industrial bodies as given in public hearings with reference to legal definitions and standards for food. Again sole discretionary power is allotted the Secretary of Agriculture to interpret as he sees fit.

SEC. 12 (a). Whenever the Secretary finds that the distribution in interstate commerce of any class of food, drugs, or cosmetics may, by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health", * * * "to hold a permit conditioned on compliance with such regulations." * * *

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, * * * and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

Objection: Notwithstanding the admitted high standards now maintained by American food, drug, and cosmetic manufacturers it is proposed to saddle upon American industry a yoke in the form of a permit system, which is probably the most dominant and all-inclusive yoke ever aimed at American commerce.

SEC. 13 (a). * * * officers or employees duly designated by the Secretary, * * * are authorized (1) to enter any factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed, * * * and (2) to inspect * * * methods, processes, finished and unfinished materials, containers, and labels there used or stored.

Objection: Regardless of the financial hazards involved, manufacturers of food, drugs, and cosmetics will be compelled at the arbitrary discretion of the Secretary of Agriculture to submit to inspection at any time and disclose perfected methods and processes. Section 12 (b) (1) the wildest injunction power ever invoked under any statute will empower the Secretary of Agriculture to deal out to American manufacturers summary trial and punishment in immediate court procedure.

SEC. 15. Investigation and institution of proceedings:

Objection: Permits any minor employee of the Department of Agriculture as well as any health, food, or drug official of any State or Territory to bring proceedings against any manufacturer, and further does not require the Secretary of Agriculture to give notice before institution of any seizure or injunction except in criminal cases.

SEC. 16. Seizure:

Objection: Any specific violation as provided for regarding misbranding, adulteration, labeling, advertising, or all of them, make the manufacturer subject to heavy fine and punishment regardless of how blameless or unintentional the error may be. Officials of the United States Department of Agriculture, etc. are relieved of civil liability.

SEC. 17. Penalties:

Objection: The conclusion is unescapable that no matter how innocent or flagrant the violation may be the act is empowered to inflict unreasonable and inhuman penalties upon every possible violator including the manufacturer, wholesaler, retailer, carrier, advertiser, advertising agency, publisher or radio broadcaster, and the dissemination of any false literature or advertisement through the mail will subject the violator to aforesaid punishment.

SEC. 18. Liability of Corporate Officers:

Objection: The slightest infraction or omission on the part of any employee is construed as the act of a corporation and all officers of such corporation regardless of innocence are subject to fine and imprisonment for any violation.

SEC. 21. Publicity:

Objection: The most dangerous latitude is permitted the Secretary of Agriculture to publish, disseminate and broadcast such information regarding charges and proceeding against manufacturers as in his arbitrary discretion would work for the public health and the protection of the consumer.

SEC. 24. Liability for personal injuries:

Objection: The inclusion of this section regarding the right of any person to sue for alleged injuries resulting from the use of food, drugs, and cosmetics opens a wide field to harass prominent manufacturers.

Giving all due credit to the gallant efforts of our President to revive American commerce, and acknowledging the undoubted ability of the Secretary of Agriculture to wisely enforce the provisions contained in this proposed act, it is yet our opinion that powers so broad and comprehensive should not be alloted to the determination of one individual, and we protest the theory of government that finds it necessary for the protection of the American consumers to ruthlessly confiscate and destroy the fruitful returns of the American manufacturers. The proposed revision of the Federal Food and Drugs Act of 1906 not only places too much power in the hands of one individual, but in the case of subordinates such power will undoubtedly lead to the opportunity and likelihood of its abuse. The bill is objectionable further because no matter how well intended its enforcement may be it is still subject because of its vague and uncertain language to limitless interpretations, and it determines in large spheres and broad general terms, which are subject to rounding out and expanding many decisions which should be definite and detailed in character. And not the least of the objections is the fact that it denies the right of individuals and businesses to the protection of the constitutional guarantees of law and freedom which are inseparable from American tradition.

As evidence of the tremendous responsibilities and autocratic decisions for which the Secretary of Agriculture will be accountable it is wise to remember among his powers are the decisions of (1) whether a food, drug, or cosmetic is or is not dangerous to health, (2) whether any product contains injurious substances or not, (3) whether labeling on any package is honest or not, (4) whether or not employees of the Department should be empowered to investigate private formulas, methods, and processes of manufacturers that have taken years to develop, (5) whether any ingredient is pure or impure, (6) whether self-medication is desirable or otherwise, (7) whether the divided medical opinion of thousands of American doctors shall be considered or whether the dictum of the Secretary of Agriculture shall be final, (8) whether an advertisement creates a "false impression" or not, (9) whether a radio broadcaster exceeds the truthful powers or not, (10) whether or not the business establishments of manufacturers should be licensed, (11) whether the accumulation of this massive power in one individual is a colossal legislative blunder or not, and (12) whether the enforcement of this proposed legislation will result in remedying the evils it professes to correct or will actually create an unwarranted destruction of capital, wages, and property.

It is entirely within reason to assume that immediately upon the passage of the proposed revision of the Federal Food and Drugs Act of 1906 the various State food and drug officials will demand that wide and arbitrary powers alloted to the Secretary of Agriculture shall be duplicated in their person, and that they will exercise every possible prerogative to enforce the most drastic interpretations possible under the revised act.

The Federal Government after all has a responsibility of restraining the ill-advised acts of minor bodies, and the manufacturers of America have every reason and right to demand that no statute be adopted which will permit local organization or individuals to exercise unlimited powers within their bodies.

It is a tradition of American industrial history that the cooperation of the food, drug and cosmetic manufacturers of the United States in their compliance with Federal statutes has always been a voluntary act. It is now proposed that they shall be regimented and coerced under the threats of fine and imprisonment. It is our contention that such a proposal is un-American, confiscatory, and unwise. And we protest the passage of this measure on behalf of thousands of American manufacturers, who are law abiding and constructive and desire to perpetuate the great principles of American industrial freedom.

It was my recommendation at the last time we had a hearing, in May, that the Department of Agriculture submit a proposed revision of the law to all of the industries involved, and then at a later date hold a meeting, at which time an opportunity would be given to the manufacturers to make recommendations. I believe at this time, in view of the large number of amendments that have been recommended, that likewise a meeting should be held between the Department of Agriculture that represents the consumers and the manufacturers, and that they be permitted to report back with a compromised bill.

The CHAIRMAN. We are very much obliged, Mr. Hall, Now, I presume you are going to present a brief pointing out changes which you think should be made in the bill before us?

Mr. HALL. Yes.

30390—34——20

The CHAIRMAN. All right.

I hold in my hand a rather interesting letter just handed to me by Senator Walcott. It comes from the Connecticut Oyster Farms Co., signed by the president, William H. Raye. Mr. Raye points out that in natural foods such elements as arsenic and copper are normally found, in sea foods particularly, and he is worried for fear there might be some percentage of tolerance formulated which would interfere.

Of course, there would be no thought on the part of the Department to interfere with natural foods in this respect.

This letter will be read into the record.

(The letter referred to by the chairman is as follows):

THE CONNECTICUT OYSTER FARMS COMPANY

Growers and Shippers of Opened and Shell Oysters

MILFORD, CONN., *December 5, 1933.*

Hon. FREDERIC C. WALCOTT,
Senate Office Building,
Washington, D.C.

MY DEAR SENATOR WALCOTT: I am quite disturbed over the possible effect on the seafoods industry of S.B. 1944, known as the Tugwell Food and Drug Bill.

The bill apparently is designed to correct some of the abuses which exist in the present Food and Drug Act, but carries so far in its scope as to practically set up arbitrary control over all foods, as well as drugs and cosmetics.

In substance, it provides complete control over the food industry under sections 3, 7, 11, and 21, by giving the Food and Drug Division of the Department of Agriculture full authority to determine what may be dangerous to health, to fix standards governing the amount of toxic elements which foods may contain, and the right to prescribe labelling which, in many instances, might compel descriptive labels of such a character as would prevent the sale of the products. In short, it contemplates bureaucratic control over the entire food industry and offers too much opportunity for political tampering with the sale of seafoods.

Seafoods, in their natural state, carry arsenic, copper, and other elements to a greater extent than do land products. At the present time there exists a so-called "world tolerance" for arsenic of 0.01 grain of arsenious oxide per pound of food. This standard dates back to 1900, when in England and Wales many people were made ill by the consumption of beer containing arsenic, and I believe this has been accepted as a tentative standard by the Food and Drug Division of the Department of Agriculture in their effort to regulate the use of insecticide sprays on farm products. The following table shows the quantities of arsenious oxide in grains per pound of various seafoods, from which you will note that all our common varieties of seafoods contain arsenic in excess of the so-called "world tolerance":

Product:	*Grains As_2O_3 per pound or pint*
Codfish	0. 0140–0. 0380
Eels	. 0180
Haddock, smoked fillet	. 0392
Mackerel, fresh	. 0136
Prawns	. 0250
Sardines, canned	. 0105– . 0200
Irish moss	. 0140– . 0590
Clams	. 0104– . 0160
Crab meat	. 0140– . 0770
Lobster	. 0160– . 1260
Oysters	. 0100– . 0165
Shrimp	. 0170– . 0770

While it is probable that the Food and Drug Division would recognize the great distinction between "added" toxic elements and such elements as arsenic and copper, when found in a natural food, nevertheless arbitrary authority granted to anybody might very well work a serious hardship upon one of our most important industries. The seafood industry ranks third in the per capita consumption of flesh foods, being exceeded only by pork and beef; it employs over 200,000 men in its various branches, and seafoods have from time immemorial been considered as healthful and as carrying many of the mineral elements

which are now lacking in our land products. Our very nation itself owes its existence to the abundance of seafoods available for the early settlers, and it seems that we are moving into dangerous ground when we grant to any controlling body the right to say that seafoods are unsafe because of the elements natural to them.

So far as I can learn, there is no published work to prove that natural arsenic in marine food results in any harmful physiological effect, and certainly a food which provides iodine and other mineral salts, which are lacking in land foods because of a soil deficiency occasioned by constant leaching, should not now be thrown under suspicion. Perhaps I am unduly fearful of the standards which may be fixed by the Department, but I can see no good reason for granting any such absolute authority to any single body of men.

Various food industries are now competing keenly for their share of markets; every effort is being made to improve the plight of the farmer, but so far little has been done for the fisherman, and only recently a processing tax was suggested upon seafoods to help the farmer. What assurance have we that, under this Act, seafoods might not be embargoed under any one of the clauses which I have enumerated in the foregoing? In fact, there is altogether too much opportunity for political tampering with our industry.

I sincerely trust that you may find it consistent to oppose the passage of this measure in its present form.

Respectfully yours,

THE CONNECTICUT OYSTER FARMS CO.
WILLIAM H. RAYE, *President.*

The CHAIRMAN. The next witness is Norman S. Dillingham, representing the American Spice Trade Association. He is a 5-minute speaker.

Mr. DILLINGHAM. I have made you popular with the audience.

STATEMENT OF NORMAN S. DILLINGHAM ON BEHALF OF THE AMERICAN SPICE TRADE ASSOCIATION

Mr. DILLINGHAM. Mr. Chairman, I want to offer this brief, reading it aloud for the reason that there are certain recommendations which may possibly want to be elaborated on.

The following brief is respectfully submitted by the American Spice Trade Association through a specially appointed committee:

It has always been the purpose and aim of the American Spice Trade Association, an organization which has been in existence for 27 years, to cooperate with the Department of Agriculture to endeavor to improve quality standards of the goods which our membership imports and manufactures. Our association was in 1906 one of the first to force shippers abroad to improve the quality of merchandise offered for entry into the United States so that when processed and offered for sale to the consuming public there would be no question of its purity.

It has always been the aim and purpose of our entire membership, which comprises approximately 80 percent of the industry, to support in every way the existing Pure Food Law; and although there are certain sections in the so-called Tugwell bill to which we object, we are nevertheless in accord with its purposes and aims.

In presenting our objections to the bill, it should be understood that we are considering only those sections which apply to our particular industry—the manufacture and distribution of spices, and spice products, for edible or seasoning purposes.

It seems to us that with the addition of regulations for cosmetics to the present Food and Drugs Act, the results thereby obtained would be substantially the same, with less confusion, than by adoption of the Tugwell bill and the repeal of the present law.

Our general objections to the proposed bill relate to the following:

1. Proposed disclosure of private formulae.
2. Vesting in the Secretary of Agriculture complete autocratic powers without the right of appeal from his decisions or those of many other nonjudicial officers.
3. Definitions of false advertising.

4. Denial of reconditioning privileges. It appears to us that in section 20 we would be denied the privileges now afforded us under the present law for the reconditioning of imports of crude spices to obtain entry.

The CHAIRMAN. That was the last statement about section 20?

Mr. DILLINGHAM. It appears to us that in section 20 we would be denied the privileges now afforded us under the present law for the reconditioning of imports of crude spices to obtain entry.

In regard to the particular sections, section 6 (a)—that is the paragraph referring to misbranding—instead of paragraph (a) which is altogether too general, we suggest a paragraph providing for the reasonably prompt government approval of labels.

Section 7 (f). It is our opinion that this paragraph aims at disclosure of all formulae, and it is our opinion that the required disclosure of any formula is absolutely unjustified by any possible benefits accruing to the public and is absolutely unjust to manufacturers who have developed formulae at great expense.

The CHAIRMAN. I want to ask you a question.

Mr. DILLINGHAM. Yes, sir.

The CHAIRMAN. You represent the Spice Trade Association; are there formulas that you employ or apply in the manufacture of spices where it would be detrimental to your industry to have in the law as it is written here?

Mr. DILLINGHAM. There are, for this reason, that we have certain blends of spices which are made up into seasonings, the different ingredients of which it would be unjust to us to disclose.

The CHAIRMAN. Would you have any objection as to the department knowing about those ingredients?

Mr. DILLINGHAM: I will answer for myself personally, if the disclosure of the formula was made known, for example, to Dr. Campbell, or to a man in his position, I would not object, but I would object to having them known and broadcast through the department as a whole.

The CHAIRMAN. My recollection is that the bill had some point exempting the necessity of declaring spices, does it not?

Mr. DILLINGHAM. There is a question there which I think is capable of two answers. It does definitely say, if I may go to that paragraph——

The CHAIRMAN. Where is that?

Mr. DILLINGHAM. 7(f).

The CHAIRMAN. Yes, that is right, the very section we have before us. In lines 6 and 7, "except that spices, flavors, and artificial colors may be designated as such without naming each spice, flavor, or artificial color."

Mr. DILLINGHAM. I should like to ask this question: Is it not so that when this paragraph was put in it referred to articles like sauces and ketchups, and things of that sort? I referred in my statement to dry seasoning. Of course that semi-colon after "weight" in line 6 might cover spices as such; on the other hand, it might also mean that any sauces and ketchups which contain spices would not require that you show on your label the pepper, ginger, or what have you, but simply the word "spice."

The CHAIRMAN. Isn't it not a fact that in the use of spices there is just an infinitesimal quantity used in a given article of food, and

it would be extremely unlikely that any harm would result from its use?

Mr. DILLINGHAM. I never knew that any harm resulted from its use.

The CHAIRMAN. Have there been any complaints in your industry about your association. Have you had any complaints from the departments here or from any State health official about the ingredients contained in spices?

Mr. DILLINGHAM. We have not, so far as I know.

The CHAIRMAN. You are just fearful that something might happen to you?

Mr. DILLINGHAM. That something might happen so we would have to disclose formulas. You see, very many spice manufacturers make up seasonings, for example, under their own formulas for meat packers, etc., and if the man has a formula of his own which is better than somebody else's, it does not seem fair that he should have to disclose it.

Senator MCNARY. Where is your principal office?

Mr. DILLINGHAM. The American Spice Trade Association?

Senator MCNARY. Yes.

Mr. DILLINGHAM. 82 Wall Street.

The CHAIRMAN. I suppose your organization has been beset by manufacturers of food products who make use of spices? I have the feeling that so far as you are concerned you do not have much to worry about?

Mr. DILLINGHAM. Of course the spice industry, in so far as it is a component part of the food industry, as a whole, is a comparatively small item, but, naturally, it is of tremendous importance to those who are in it.

May I go on from there, sir?

The CHAIRMAN. Oh, yes.

Mr. DILLINGHAM. Referring now to section 9 (a), on page 12, which has to do with false advertisements, it appears to us that insofar as this article affects food in general and spice in particular this provision is too broad in its terms. This is simply in line with what others have said, and there is no need of our going into it.

The CHAIRMAN. You would prefer to take the law as it is nw witho the interpretation of the Supreme Court regarding it than to have new language?

Mr. DILLINGHAM. Insofar as it affects our industry, yes.

Section 12 (b). Line 24: Substitute the word "shall" for "may," in that sentence beginning "The Secretary may reinstate."

Section 13 (a). Line 24: Substitute a comma for the period after the word "stored" and add "provided, however, nothing herein contained shall be construed as requiring a manufacturer to disclose any formula or formulae."

Section 15 (a),—that is on page 19, line 15: Insert a period after the word "Agriculture" and delete the balance of the paragraph. Our reason for that is that this gives the employees of the Department of Agriculture the sole right to conduct investigations and takes it out of the hands of State and municipal employees, as we do not think it belongs there.

The CHAIRMAN. Would not that proposal, if adopted, throw a tremendous expense upon the Department of Agriculture which is

unnecessary because health officials elsewhere are competent to pass judgment?

Mr. DILLINGHAM. In discussing that paragraph it seemed to us that the knowledge and ability of whatever men the Department appoints as investigators will probably be of a higher type than we would be likely to get in the underemployees of the various cities and municipal health boards.

The CHAIRMAN. Is it not entirely probable that the oustide officials would give consideration to that fact?

Mr. DILLINGHAM. It would be probable, yes, if such men were available.

Senator MCNARY. Go ahead.

Mr. DILLINGHAM. Section 15 (b)——

The CHAIRMAN. Before you pass that, let me call attention to the present law, Section 5, where a provision is made for the employment of these outside officials. In other words, this is already in the law.

Mr. DILLINGHAM. I agree with you, sir.

Our next suggestion in regard to Section 15 (b), in lines 21 and 22, is that we delete from that paragraph the phrase "or to whom any health, food, or drug officer of any State or territory, or political subdivision thereof."

The CHAIRMAN. The same suggestion as the other?

Mr. DILLINGHAM. Exactly the same. Simply covers that same point.

The dictatorial powers conferred upon the Secretary of Agriculture, in our opinion, deny business its constitutional guarantees. They place the Secretary in the position of a judge and jury, with no adequate right of appeal for the accused.

We are of the opinion that it is most unfair to ask business to appeal to the official who himself makes the ruling and decision, from which appeal is taken. We should have a court of appeals fashioned somewhat along the lines of our United States Customs Court of Appeals.

The CHAIRMAN. We are much obliged to you, Mr. Dillingham.

The next speaker is Clinton Robb, counsel for the United Medicine Manufacturers of America.

Mr. Robb?

STATEMENT OF CLINTON ROBB ON BEHALF OF THE UNITED MEDICINE MANUFACTURERS OF AMERICA

Mr. ROBB. Mr. Chairman and Senators, while I am authorized to speak on behalf of the United Medicine Manufacturers of America, I shall try to reflect very briefly in a few observations that are the result of my specialization for the past several years in the laws and regulations pertaining to foods and drugs, and to some extent cosmetics. I shall try to be fair, constructive, and helpful, instead of merely critical. My whole object is one of cooperation with this committee.

Let me say at the outset that for Mr. Campbell, Dr. Cullen, and all the others who are seeing to enforcing the Food and Drug Act, I have only the highest respect, and that anything I might say here is not intended or to be construed as reflecting upon them in any way.

May I also say that what I may have to say regarding self-medication, it is not to be understood as expressing any want of appreciation or respect for that high profession which the chairman of this Committee so honors and adorns.

My first observation is that a reading of this bill and a consideration of the statements made by the proponents of it might lead one to the belief that the public now is largely at the mercy of the unscrupulous, willful violator, for whom, of course, neither my organization nor the industry as a whole has any use whatever.

Nothing could be farther from the fact; the truth is that at this moment there are functioning three thoroughly organized and thoroughly coordinated Federal agencies that are dealing very effectively, as I have good reason to know, with the willful violators.

Those three agencies are, first, the Post Office Department. It does not seem to be generally known that under the postal laws and regulations it is possible for the Government in a case where the manufacturer is using the mails to sell direct to a consumer, as any large manufacturer often may have to do, it is possible for the Government to reach and punish and stop the business of a manufacturer who is merely sending a package to another point in the same State; in other words, one who is doing a clearly intrastate business, which could not be reached under the Foods and Drugs Act.

Senator MCNARY. What do you think about this bill?

Mr. ROBB. I am coming to that very briefly.

Senator MCNARY. Let us have it now.

Mr. ROBB. Turning to section 8, the requirement is in effect that a product is to be considered as misbranded unless the manufacturer states that the product is not a cure. It is a well known fact that even physicians are not able to cure, that nature alone can cure, and that the physician cannot do any more than assist nature.

If the drug had to bear a label that it was not a cure, I submit that the manufacturer would have no better chance of selling that product than the physician would have of selling his services if he had to place over the door of his office, "I do not cure." That is with all due respect to the Chairman.

Now, if this industry is to be liquidated, let us do it expeditiously and directly instead of through what I may describe as an added poisonous or deleterious ingredient in this statute.

The CHAIRMAN. Now, Mr. Robb, I know you want to be perfectly fair——

Mr. ROBB. I certainly do, Senator.

The CHAIRMAN. The department has in mind that there should not be the privilege on the part of manufacturers or advertisers to set out to cure incurable ailments.

Mr. ROBB. Neither do I. I haven't any use for the man who does.

The CHAIRMAN. All right. Then you suggest how we can formulate the bill in a way to accomplish what you have in mind without invading the field of common decency.

Mr. ROBB. I was attempting to develop that, and I rather have interrupted the argument I expected to make. If I may be indulged I shall be glad to try to do it and very quickly.

Now, under the present Food and Drugs Act, and particularly since the decision of the Supreme Court of the United States through the then justice, now chief justice, Hughes, Congress deliberately excluded

the field of honest differences of opinion between schools of practitioners.

Now, theoretically, a manufacturer may rely upon the opinion of a minority of the profession. It is conceivable, theoretically, that the views of only 10 percent of the medical profession, if backed by outstanding figures in the profession, might warrant the manufacturer in putting out his product based upon those views.

Now, what is the practical situation? I think it is a situation which you might be interested in a typical case. The manufacturer has a preparation which represents the prescription of a practicing physician. He employs a competent chemist to help him perfect the development of that product. He in turn submits that formula to other physicians and improvements are made.

He is summoned by the Government and informed that his claims are regarded as extravagant and untrue. He employs counsel and counsel advises him after careful consideration of the case that he is warranted in making these claims. Now, what happens?

It is true that he has a right to go to court, but before he can get a judicial determination of this difference of opinion that may exist between him and the department, his business may be absolutely destroyed through the seizure of his product.

Now, we maintain that that is unfair and it is un-American.

Where there are honest differences of opinion between the manufacturer and the Government there ought to be an independent tribunal that would give a summary decision that would be binding unless that decision was reversed by a court.

I propose to show very briefly that under the terms of the statute even the rights that he now has would be taken away from him.

I will turn back, if you please, to section 8: "A drug shall be deemed to be misbranded"——

The CHAIRMAN. What section is this?

Mr. ROBB. Section 8, Mr. Chairman, line 22: A drug shall be deemed to be misbranded if it is contrary to the general agreement of the medical profession.

Now, I feel sure that the observation and experience of this committee has been the same as mine, that the adoption of the new and the improved usually, and almost always, is by the minority.

The CHAIRMAN. Pardon me, Mr. Robb. Were you here yesterday?

Mr. ROBB. Yes, sir.

The CHAIRMAN. You will remember that the last witness last night went into that very extensively.

Mr. ROBB. Johnson Beale?

The CHAIRMAN. Yes. For your comfort let me say, if it is any comfort, that I share this view that you have about the impossibility of any unanimity of medical opinion, contemporary or ancient.

Mr. ROBB. Thank you very much, Mr. Chairman. Then the industry will hope that when this bill is given final form it will be so revised that it will not be necessary for the manufacturer to risk his business and his liberty by being found out of harmony with the general agreement of the medical profession.

The CHAIRMAN. Do you feel if the bill were enacted as it were written here it would ruin the industry?

Mr. ROBB. I certainly do. I think it would absolutely ruin the industry. I think it would be a practical impossibility for a manufacturer to continue in business.

The CHAIRMAN. Are there no restrictions now upon what you can do and how far you can go?

Mr. ROBB. There are restrictions.

The CHAIRMAN. When they were imposed did the business suffer?

Mr. ROBB. Business did not suffer from the imposition of reasonable requirements. I am not here to maintain for a moment that everything is exactly as it should be in the industry and that no act is necessary. That is not my attitude at all.

The CHAIRMAN. You remember the old lady who had stock in the undertaking concern and found fault because the returns were not good? Have we got to take off the safeguards? Is not this bill in the interests of the public? Are we not here to guard the interests of the public?

Mr. ROBB. Let me say frankly and directly, Senator, that we are unwilling that the proponents of this bill should claim all of the available credit for being in favor of the protection of the public health. So are we. That is the very reason why we are offering our remedies to the public.

(There was a short pause.)

Mr. ROBB. It is like the preacher who preached the sermon on sin; we are against it but we are a little concerned with the definition of what is sinful and with the question of who is going to decide.

The CHAIRMAN. All right, Mr. Robb, very good. Have you finished your statement?

Mr. ROBB. On that section 8, I have; yes.

The CHAIRMAN. What is the next point?

Mr. ROBB. If you will turn, Senator, to page 13, section (c):

> To discourage the public advertisement for sale in interstate commerce for drugs for diseases wherein self-medication may be especially dangerous or patently contrary to the interests of public health—

Now, I ask the committee with all frankness and sincerity what the plain implication of that language is? Is there any escape from the conclusion that the framers of this section think that every patent medicine is dangerous but that some are especially or patently so? There is no escape from the conclusion.

Now, we ask the committee——

The CHAIRMAN. We go further and we actually put it in the bill on the next page.

Mr. ROBB. Then follows a long list of diseases. Now, let me say right here that up to this moment the course followed considering the permissible scope of self-medication have always made a distinction between ailments which are infectious or contagious and those which are noncontagious and I challenge the opposition to produce a single case in which a court has ever held self-medication is inherently or otherwise dangerous with respect to any ailment not of a communicable nature.

Yet, the provisions of this act would sweep away all that the courts have found for a quarter of century and we would have to start all over again. During the last 25 years the best legal minds in the country, represented by the judges of our Federal courts have given careful, thoughtful consideration to the numerous questions that have arisen

under the present act, but if we are to throw that statute into the waste-basket we must start all over again; we must lose the benefit of what these men have given us.

Now, I will repeat that I think some action may be called for, but let us take the old statute and plug out the holes that have been found in it and make the protection of the consuming public just as full and complete as is possible.

We certainly wish to cooperate with you to the best of our ability to do so.

The CHAIRMAN. Thank you very much, Mr. Robb.

Mr. ROBB. May I say—there are just one or two other things I have here. I will not be long, Senator. There are just one or two other things that I want to say.

Now, if you will turn to page 31 you will find there this statement, which I think to be a very dangerous provision:

> The findings of fact by the Secretary shall be conclusive if in accordance with law.

The CHAIRMAN. You remember that that has been modified by the Department itself.

Mr. ROBB. Yes, but even as modified I do not think it goes far enough.

You recall, Senator, that in the provision respecting the Interstate Commerce Commission and the Federal Trade Commission, these bodies are made fact-finding bodies and their findings of fact shall be conclusive—when? When supported by substantial evidence. That ought to be the provision here. All that this language requires of the secretary is that he should observe the formalities. Even though his decision may represent only 10 percent of the evidence, his findings would be absolutely conclusive, and under this language. If the secretary is to be made the fact-finding instrumentality then his decisions should be supported by substantial evidence.

The CHAIRMAN. If they were unreasonable would they not be subject to court review?

Mr. ROBB. Under this language, and I speak after thorough study of this section, it would be impossible for the court to upset the decision; whereas, if the provision is that the findings shall be supported by substantial evidence, then the court will have power to weigh.

I may say as a member of the National University Law School Faculty and as a lecturer on the jurisdiction and practice of the Federal Trade Commission for many years, I have had occasion to consider very carefully this very question and I feel that the findings of fact of the secretary are to be conclusive there should be a requirement that they be supported by at least substantial evidence.

Now, just a word in conclusion. I hope I may have the opportunity to supplement my statements with a brief.

The CHAIRMAN. We will be glad to receive the brief.

Mr. ROBB. I want to say that the industry, and I speak particularly of the efforts of my own organization, have been trying for years to standardize food and drugs products. We have made a lot of headway and I think Mr. Campbell will bear me out when I say that conditions are far better today than they were a little while ago.

Here is a final thought that I want to leave with the Committee. We are going to have a code now, and with this added instrumentality

if we are given the opportunity we will show you in a short time that the industry is not only on a par with all the others, but is a model.

I thank you.

The CHAIRMAN. Thank you, Mr. Robb.

The brief subsequently submitted by Mr. Robb, follows:

BRIEF ON BEHALF OF THE UNITED MEDICINE MANUFACTURERS OF AMERICA

1. Unless the bill takes the form of an amendment to the existing Food and Drugs Act, following the general plan of the original statute, all the decisions of our Federal courts construing and applying that statute during the last 27 years will be set at naught, with complete sacrifice of benefit from the thoughts and ideas of some of the country's best legal minds respecting the problem of regulating the manufacture and sale of food and drug products. For example, such terms as "therapeutic" and "curative" should be preserved in the new statute because the courts have been at great pains to define them with exactness.

2. The bill should preserve the public's right to self-medication by relieving manufacturers of drug products of the necessity of showing that their claims are in accord with the general agreement of the medical profession. In enacting the Food and Drugs Act of 1906 the Congress carefully safeguarded that right, as observed by the Supreme Court speaking through Justice (now Chief Justice) Hughes:

"Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners." (*Seven Cases* vs. *U.S.*, 239 U.S. 510, 517.)

3. Multiple seizures of drug products at widely scattered points, subjecting manufacturers with limited resources to prohibitive expense in making their defense to charges of misbranding, should be prohibited except in flagrant cases. Any provision in the bill for court review of administrative decisions, in cases of honest differences of opinion between a manufacturer and the Food and Drug Administration as to the therapeutic powers and uses of a product, will be an empty right to the average manufacturer unless the bill makes it possible for that manufacturer to preserve his business pending such court review. The creation by the Congress of some independent board, whose summary decisions on appeals from administrative rulings of the Food and Drug Administration would be binding upon both the Government and the manufacturer unless and until set aside or modified by a court, would protect all the parties in interest.

4. Inasmuch as the interest of the medical profession necessarily conflict in some degree with those of manufacturers of prepared medicines, and since the profession under the leadership of the American Medical Association is publicly committed to the theory that all self-treatment is inherently dangerous unless under the supervision of some physician, the average physician naturally and unconsciously is more or less prejudiced against the sale of prepared medicines to laymen. Therefore, and as the Secretary of Agriculture would depend upon the medical advisers of the Food and Drug Administration in his decisions regarding the permissible scope of self-treatment in general and of some drug or medicine in particular, the decision of questions of therapeutic worth or medicinal value should be committed by the Congress to some board or body independent of medical influence. The courts, mindful of the fact that physicians are interested parties and subject to unconscious prejudice in questions involving self-medication, have consistently declined to hold that self-medication is dangerous unless practiced under conditions which give rise to reasonable apprehension as to contagion and the spread of disease.

5. As to advertising independently of the package, as in newspapers and magazines, both the Federal Trade Commission and Post Office Department are now actively censoring false and misleading claims respecting foods, drugs, and cosmetics; and in deciding questions of medicinal value those two Federal agencies are not governed entirely by medical opinion, as is the Food and Drug Administration, but weigh all considerations in a judicial manner. Existing laws curb and punish willful violators.

Since the Federal Trade Commission was created it has had occasion to pass upon about 1,800 cases involving false and misleading advertising. The fact that more than 80 percent of those cases involved commodities other than foods, drugs or cosmetics indicates that the prepared medicine industry is less given to extravagant advertising than are some other industries. Certainly the experience of the Federal Trade Commission reveals no necessity or occasion for sin-

gling out manufacturers of drug products for the imposition of additional or special handicaps with respect to advertising.

The prepared medicine industry neither asks nor expects special favors from Congress, but it respectfully protests against unnecessary discrimination. If and when Congress in its wisdom concludes that all advertising should be under Federal censorship, manufacturers of packaged medicines will be fully prepared to observe both the letter and the spirit of such general requirements as may be imposed. All that the industry asks is that it receive like treatment with other industries.

6. Some manufacturers already voluntarily disclose their active ingredient formulas but there is strong objection in the trade to such a requirement in the new bill. It is felt that to require public disclosure of the quantities of ingredients and the publication of working formulas, thereby inviting trade piracy and jeopardizing valuable and honestly acquired good will, would impose an unnecessary handicap that would be to the ultimate disadvantage of the purchasing public.

7. No valid objection is seen to a requirement in the new bill that each manufacturer of foods, drugs, and cosmetics file with the Food and Drug Administration information as to his experience and responsibility, as well as to the nature of such products as he is selling or expects to sell to the public. But no necessity or sound reason is apparent for a permit system that, in effect, would give to the Secretary of Agriculture power to compel every manufacturer to agree to any terms the Secretary might impose, regardless of what might be their arbitrary or unduly harsh nature, upon penalty of the destruction of his good will pending judicial relief if he resisted.

The United Medicine Manufacturers of America, Inc., a trade association composed of representative manufacturers throughout the United States, hereby pledges its full and unconditional support to any measure that will add in any degree to the protection of the public health and the advancement of the public interest. All that the industry asks of the Congress of the United States is that due consideration be given to its rights and that the good will of honest manufacturers be not subjected to danger of complete destruction merely because of the propensities of a few willful violators.

Respectfully submitted.

CLINTON ROBB, *Counsel.*

The next witness is Mr. C. C. Parlin, of Philadelphia, representing the National Periodical Publishers. Mr. Parlin.

STATEMENT OF C. C. PARLIN ON BEHALF OF THE NATIONAL PERIODICAL PUBLISHERS

Mr. PARLIN. Mr. Chairman, I am Charles Coolidge Parlin, manager of the Division of Research of the Curtis Publishing Co., representing the National Publishers' Association, which is composed of about 150 publications with an aggregate circulation of 50 million. I submit herewith a list of the members.

The CHAIRMAN. It will be included in the record.

(The membership list is as follows:)

MEMBERSHIP LIST NATIONAL PUBLISHERS ASSOCIATION, 232 MADISON AVENUE, NEW YORK, N.Y., OCTOBER 3, 1933

Advertising Age, 537 South Dearborn Street, Chicago, Ill.
American Bankers Association Journal, 22 East Fortieth Street, New York, N.Y.
American Boy, 7430 Second Boulevard, Detroit, Mich.
American City, 470 Fourth Avenue, New York, N.Y.
American Hairdresser, 386 Fourth Avenue, New York, N.Y.
American Journal of Nursing, 450 Seventh Avenue, New York, N.Y.
American Medicine, 18 East Forty-first Street, New York, N.Y.
American Mercury, 730 Fifth Avenue, New York, N.Y.
American Trade Publishing Co., 45 West Forty-fifth Street, New York, N.Y.:
- Bakers' Weekly
- Cracker Baker

Architectural Record, 119 West Fortieth Street, New York, N.Y.
Asia, 468 Fourth Avenue, New York, N.Y.
Atlantic Monthly, 8 Arlington Street, Boston, Mass.
Best's Insurance News, 75 Fulton Street, New York, N.Y.
Better Homes and Gardens, Des Moines, Iowa.
Boys' Life, 2 Park Avenue, New York, N.Y.
Casket and Sunnyside, 487 Broadway, New York, N.Y.
Chief, The, 2 Lafayette Street, New York, N.Y.
Child Life, 536 South Clark Street, Chicago, Ill.
Choir Leader, 501 East Third Street, Dayton, Ohio.
Conde Nast Publications, 420 Lexington Avenue, New York, N.Y.:
- House and Garden
- Vanity Fair
- Vogue

Confectioners Journal, 437 Chestnut Street, Philadelphia, Pa.
Credit and Financial Management, 1 Park Avenue, New York, N.Y.
Crowell Publishing Company, 250 Park Avenue, New York, N.Y.:
- American
- Collier's Weekly
- Country Home
- Woman's Home Companion

Cumulative Book Index, 958 University Avenue, New York, N.Y.
Curtis Publishing Co., Independence Square, Philadelphia, Pa.:
- Country Gentleman
- Ladies' Home Journal
- Saturday Evening Post

Delineator, 161 Sixth Avenue, New York, N.Y.
Dun and Bradstreet Monthly Review, 290 Broadway, New York, N.Y.
Econostat, The, 21 West Street, New York, N.Y.
Electrical Contracting, 520 North Michigan Avenue, Chicago, Ill.
Etude, The, 1712 Chestnut Street, Philadelphia, Pa.
Farm Journal, Washington Square, Philadelphia, Pa.
Field and Stream, 578 Madison Avenue, New York, N.Y.
Financial Age, 132 Nassau Street, New York, N.Y.
Financial World, 53 Park Place, New York, N.Y.
Florists Exchange and Horticultural Trade World, 448 West Thirty-seventh Street, New York, N.Y.
Forbes Magazine, 120 Fifth Avenue, New York, N.Y.
Forum, 441 Lexington Avenue, New York, N.Y.
Gospel Trumpet, Fifth and Chestnut Streets, Anderson, Ind.
Domestic Engineering, 1900 Prairie Avenue, Chicago, Ill.
Gregg Writer, 270 Madison Avenue, New York, N.Y.
Grit, Williamsport, Pa.
Harper's Magazine, 49 East Thirty-third Street, New York, N.Y.
Hat Trade Publishing Co., 1225 Broadway, New York, N.Y.:
- American Hatter
- Millinery Trade Review

Heating, Piping, and Air Conditioning, 1900 Prairie Avenue, Chicago, Ill.
Hotel Management, 220 East Forty-second Street, New York, N.Y.
Household Magazine, Capper Building, Topeka, Kans.
Instructor, The, Dansville, N.Y.
International Magazine Co., Fifty-seventh Street and Eighth Avenue, New York, N.Y.:
- American Architect
- Cosmopolitan
- Good Housekeeping
- Harper's Bazaar
- Motor
- Motor Boating

Keystone, 1505 Race Street, Philadelphia, Pa.
Laundry Age, 1478 Broadway, New York, N.Y.
Life, 60 East Forty-second Street, New York, N.Y.
Literary Digest, 354 Fourth Avenue, New York, N.Y.
McCall's Magazine, 230 Park Avenue, New York, N.Y.

McGraw-Hill Publishing Co., 330 West Forty-second Street, New York N., Y.
American Machinist
Aviation
Chemical & Metallurgical Engineering
Coal Age
Electrical Merchandising
Electrical World
Engineering & Mining Journal
Engineering News-Record
Power
Transit Journal
Macfadden Publications, 1926 Broadway, New York, N.Y.:
Physical Culture
True Story
Machinery, 140 Lafayette Street, New York, N.Y.
Modern Beauty Shop, 608 South Dearborn Street, Chicago, Ill.
Modern Hospital, 919 North Michigan Avenue, Chicago, Ill.
Motion Picture Publications, 1500 Broadway, New York, N.Y.:
Motion Picture
Movie Classic
National Petroleum News, 1213 West Third Street, Cleveland, Ohio
National Provisioner, 407 South Dearborn Street, Chicago, Ill.
National Sportsman, 408 Massachusetts Avenue, Boston, Mass.
National Underwriter, A-1946 Insurance Exchange South, Chicago, Ill.
National Sportsman, 408 Massachusetts Avenue, Boston, Mass.
National Underwriter, A-1946 Insurance Exchange South, Chicago, Ill.
Nation's Business, 1615 H Street, N.W., Washington, D. C.
Needlecraft Magazine, Augusta, Maine.
News-Week, 1270 Sixth Avenue, New York, N.Y.
New Yorker, The, 25 West Forty-fifth Street, New York, N.Y.
New York Lumber Trade Journal, 285 Madison Avenue, New York, N.Y.
Northwestern Miller and American Baker, 118 South Sixth Street, Minneapolis, Minn.
Open Road for Boys, 130 Newbury Street, Boston, Mass.
Outdoor Life, 111 East Hitt Street, Mount Morris, Ill.
Parents' Magazine, 114 East Thirty-second Street, New York, N.Y.
Movie Makers, 105 West Fortieth Street, New York, N.Y.
Penton Publishing Co., Penton Building, Cleveland, Ohio.:
Abrasive Industry.
Foundry.
Marine Review.
Power Boating.
Steel.
Periodical Publishing Co., 200 Division Avenue, North Grand Rapids, Mich.:
Furniture Manufacturer
Furniture Record and Journal
Photo-Engravers Bulletin, 166 West Van Buren Street, Chicago, Ill.
Pictorial Review, 214 West Thirty-ninth Street, New York, N.Y.
Pipe Line News, 1217 Hudson Boulevard, Bayonne, N.J.
Playthings, 381 Fourth Avenue, New York, N.Y.
Popular Mechanics, 200 East Ontario Street, Chicago, Ill.
Popular Science Monthly, 381 Fourth Avenue, New York, N.Y.
Postage and The Mailbag, 200 Fifth Avenue, New York, N.Y.
Pottery, Glass & Brass Salesman, 160 Fifth Avenue, New York, N.Y.
Printers' Ink Monthly, 185 Madison Avenue, New York, N.Y.
Progressive Farmer and Southern Ruralist, Birmingham, Ala.
Publishers Weekly, 62 West Forty-fifth Street, New York, N.Y.
Review of Reviews, 233 Fourth Avenue, New York, N.Y.
Robbins Publishing Co., 9 East Thirty-eighth Street, New York, N.Y.
Advertising and Selling.
American Printer.
Gas Age-Record.
Rudder, The, 9 Murray Street, New York ,N.Y.
Saturday Review of Literature, 25 West Forty-fifth Street, New York, N.Y.

W. R. C. Smith Publishing Co., 1021 Grant Building, Atlanta, Ga:
Cotton.
Southern Power Journal.
Southern Hardware and Implement Journal.
Specialty Salesman Magazine, 307 North Michigan Avenue, Chicago, Ill.
Sportsman, The, 60 Batterymarch, Boston, Mass.
Standard Publishing Co., Eighth and Cutter Streets, Cincinnati, Ohio:
Christian Standard.
Lookout.
Starchroom Laundry Journal, 415 Commercial Square, Cincinnati, Ohio.
Sunday School Times, 325 North Thirteenth Street, Philadelphia, Pa.
Theatre Arts Monthly, 119 West Fifty-seventh Street, New York, N.Y.
Time, 135 East Forty-second Street, New York, N.Y.
Toilet Requisites, 18 Rockefeller Plaza, New York, N.Y.
Travel, 4 West Sixteenth Street, New York, N.Y.
United Publishers Corporation, 239 West Thirty-ninth Street, New York, N.Y.:
Automobile Trade Journal.
Automotive Industries.
Boot and Shoe Recorder.
Dry Goods Economist.
Hardware Age.
Iron Age.
Jewelers' Circular.
Optical Journal and Review of Optometry.
Spectator.
Upholsterer and Interior Decorator, 373 Fourth Avenue, New York, N.Y.
Variety, 156 West Forty-sixth Street, New York, N.Y.
War Stories, 100 Fifth Avenue, New York, N.Y.
Weekly Underwriter & Insurance Press, 80 Maiden Lane, New York, N.Y.
Yachting, 205 East Forty-second Street, New York, N.Y.

Mr. PARLIN. This includes the names of practically all magazines with large advertising revenue.

The National Publishers Association voices the hearty approval of legislation to protect health and also voices its hearty approval of legislation to prevent false advertising of foods, drugs, and cosmetics.

Leading magazines actively worked for the Food and Drugs Act of 1906. They would today, I believe, be actively working for this bill if it had been confined to phases needful to protect health and to stop false advertising.

Mr. Chairman, you have stated that you did not write the bill and that many amendments will be made to the bill.

The CHAIRMAN. As I said, if I had my way, they would be made. You must remember I have colleagues on the committee.

Mr. PARLIN. We will accept the amendment.

It is quite possible, Mr. Chairman, that after you have rewritten the bill, if your colleagues allow you to do so, we may be as strongly in favor of it as we are now opposed to it.

Since advertising for the first time faces the imposition of a Federal criminal statute, I beg leave before offering objections to particular clauses, very briefly to state a few facts concerning advertising which I think are essential to have in mind in interpreting the specific objections we offer to this bill.

Manifestly, selling and advertising and manufacturing have grown up in this country hand in hand. Advertising is not a mere adjunct to business, it is a vital part of business. It furnishes the forward look, the imagination, the enthusiasm. It expresses the hopes, the aspirations and the executive thinking of concerns, both great and small.

Advertising not only prepares the way for sales, it vitalizes every part of the business. Furthermore, advertising sets up for concern a high standard of quality from which the manufacturer dare not depart.

In these standards the manufacturer comes to take great pride, and out of this fact, more than any other, has come the marvelous evolution to better products which has been one of the outstanding features of our day and generation.

What got the cat out of the sugar barrel, converted bulk goods into packaged form, and changed unsanitary food shops into neat, attractive, and wholesome grocery stores? With all due deference to good work done by Federal and State Governments, I believe I am quite right in asserting that advertising was the largest factor in producing this transformation. When manufacturers attractively advertised the sanitary and appetizing qualities of their packaged foods, the public would no longer tolerate unsanitary and unappetizing sales methods.

What produced the finest food factories in the world? Again, with due credit to good work by Federal and State Governments in insisting that all factories live up to minimum standards, may I claim primary credit to advertising for producing exceptional factories including many of the finest food kitchens in the world?

So, I might go on from industry to industry, and in the end I would feel justified in declaring to you as my belief that the greatest single factor in making American economic life what it is today has been advertising.

May I also say that as advertising has grown powerful, it has improved in character and tone? Forty years ago a large part of national advertising would not measure up to modern standards. Today only a small portion deserves elimination through criminal statute.

There is no popular demand to curb the great advertisers. They are not in the Chamber of Horrors. Their brand names are household words. Among all classes, advertised products are held in respect and their producers are looked upon as benefactors.

No person is compelled to buy advertised products. The great American public of its own free will and accord gladly and enthusiastically buys advertised products because advertised products give excellent value at reasonable prices.

Forty years ago the wise person read advertising with suspicion. He had sent a dollar and been buncoed. The wise person today reads advertising discriminately and believingly. He is not deceived by a bit of imagery; he does not readily fall for quackery; he quickly detects a false note, but fundamentally he reads product advertising with confidence. He has not been buncoed. He has bought advertised products and found them satisfying.

May I tell you why advertising has improved and why the readers of advertising quite consistently obtain worthy products? It is not the result of policing. It has been brought about by the very simple fact that no manufacturer can afford to advertise a product for which he cannot win repeat customers and, at least in most lines of merchandise, no manufacturer can win repeat customers unless his product has merit and a reasonable price.

May I also say one other thing. For the span of more than a generation, a considerable number of publications have made a sincere effort to protect their readers against unworthy products and untruthful advertising. These publications will lose little if any

revenue by legislation that puts the Chamber of Horrors out of existence. If that was all that Senate bill 1944 was designed to do, these publications would not today appear in opposition to the measure.

It is because this bill has provisions which they believe will damage the whole structure of national advertising and will bring serious harm to customers, to manufacturers and to publishers and which they believe will throw thousands out of employment, that they join their voices with those of other publicity interests to express their most emphatic protestations against Senate bill 1944 as it is now drawn.

The two features of Senate bill 1944 to which above all others we emphatically object are:

(1) The definition of false advertising (Section 9 (a)—False Advertisement).

(2) The provision authorizing the establishment and promotion of grade A, grade B, and grade C on foods.

The authority for this is not explicitly stated in the bill but is to be found in a combination of three sections, namely: Section 11 (Definitions and Standards for Food), section 22 (Voluntary Inspection), section 21 (Publicity).

May I first discuss the false advertisement? We refer to the definitions presented this morning by Mr. Dunn, which reads:

> An advertisement of a food, drug, or cosmetic shall be false or incuriously misleading in any material particular relating to the purposes of the act.

The words in the bill "in any particular" appear to us dangerous. These words, so to speak, order a judge and jury to convict for any inaccuracy, however slight and however immaterial the error may be.

The words "by ambiguity or inference creates a misleading impression" are much too vague and sweeping for a criminal act.

Such phrases are particularly harmful when applied to advertising. It is almost impossible to write an advertisement which someone may not say gave him a misleading impression. Does the picture of a log cabin give an impression that Towle's maple sirup is made in or near a log cabin? Does the picture of a Dutch woman give an impression that Old Dutch Cleanser is made in Holland?

It is beside the point to say that "in any particular" and "by ambiguity or inference creates a misleading impression" are to be found in a Supreme Court interpretation, first because the court interpretation applied to labels, and advertising presents very different problems than labels.

Second, because the courts started with misleading and got to ambiguity and influence. If the court starts again with ambiguity and influence where would they get to next time?

It is not enough to say that loose phrases have been in previous laws. We are likely now to be confronted with an attempt to enforce some of these loose phrases. Copy service, as every publisher knows, is a difficult problem—there are many border-line decisions. Matured experience is needed to apply even a definite regulation an there is, we believe, no possibility that substantial justice will be done under so vague a clause as "by ambiguity or inference creates a misleading impression."

Out of years of experience with copy service and with a sincere desire to cooperate in clearing up advertising abuses, we urge you to

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limit this statute for the present, at least, to a simple statement that "false" means "false or injuriously misleading in any material particular relating to the purposes of this act."

The question of whether a statement is true or false is a question of fact which can be accurately determined in a court.

Let us try this definition for at least 2 years until advertisers get used to the idea of Government regulation of advertising copy and until experience proves that definition to be inadequate.

Some directors are easily frightened into voting against advertising appropriations. We ask you to do nothing which may unduly alarm them.

If the clause be adopted as it now reads, we are certain to have numerous advertising appropriations negatived because of uncertainty.

All this is serious, for when sound advertising is canceled manufacturers are deprived of their right to expand their markets, publishers are deprived of advertising revenue, farmers have their markets for raw materials curtailed, workers are thrown out of employment, consumers fail to have their appetites whetted for wholesome and tasty products, and no one is benefited.

The present Food and Drugs Act deals only with labels. Let us remember that labels and advertising are two very different products.

Labels give information for use after purchase. They are, except for an occasional trade mark or an advertising slogan, cold, factual, informative, unimaginative. On the other hand, advertising is warm, it appeals to appetite, to imagination. It creates desire and impels to action.

The reduction of advertising to cold, factual statements which would pass the rigid censorship of literal minded chemists and physicists would kill advertising. For advertising would be too dull to read and manufacturers would not pay to run it.

May we suggest in all sincerity as our belief of what is really in the best interest of the Nation at this time that you pass legislation which adequately protects public health, and that you let legislation on advertising stop there.

Thereby advertisers will be relieved of a serious threat and legitimate advertising can begin again to do its powerful bit toward promoting business, rescuing people from unemployment, and restoring national prosperity.

Again I would like to speak of the establishment of grade A, grade B, and grade C.

SECTION 11. We recommend that "minimum" be inserted before "standards" (line 13-14) and before "standard" (lines 16, 17, 21, 22, and 25). In order that you may see clearly just what our objections to these sections are, may we first describe to you just what, as we understand it, the Department of Agriculture plans to do under these sections and then state our six objections to the plan.

The bill, as we understand it, makes it possible to establish for canned fruits, canned vegetables, and other food products, grades above substandard, and we understand that it is the intent of the Department of Agriculture, if this bill passes, to establish grade A, grade B, grade C, and requires every manufacturer to mark his grade on every can and package.

We wish to include the word "minimum" wherever the word "standard" occurs in the bill. As a matter of fact, we are not finicky on the word, but anything that will change this from the range of standards to a single standard is quite satisfactory to us.

The words of the McNary-Mapes amendment would be quite satisfactory in that respect to us.

To understand its full significance, this provision must be considered in connection with section 22 on Voluntary Inspection and section 21 on Publicity. In connection with these two sections, the grading provision plans an amazing invasion into the food, drug, and cosmetic industries.

Under a previous act, the Department of Agriculture established A, B, and C grades for several lines of food products and then attempted to set up a system of optional grading in the canning industry. Under this system, at the request and expense of the packer, inspectors were placed in a few canneries throughout the period of the pack, and the owners of these canneries were authorized to label these products "U.S. Grade A" (U.S. Grade B or U.S. Grade C, as the case might be) instead of merely Grade A (Grade B or Grade C). We are informed that the Department offered, if a certain small percent of the pack would agree to this optional grading, to provide Government publicity to popularize the U.S. grades used by these packers—in other words, through Government-sponsored advertising to exhort the public to select merchandise on the basis of U.S. Grade A (U.S. Grade B or U.S. Grade C) instead of by manufacturers' labels or advertised brands.

This plan, as we understand it, was blocked by the fact that according to law, the packers' payments were covered into the Treasury and so were not available to defray the continuing expense of the service, and Congress refused to vote further appropriations for this inspection service except on the condition that the packer should no longer be entitled to place the U.S. Grade on his label.

It seems to us obvious that the intent of the "Voluntary Inspection Service" section of this bill is to reauthorize the discarded "Optional Grading" plan, this time no longer hampered by the necessity for applying to Congress for appropriations to maintain it. The money is to be obtained from canners and manufacturers, receipts from inspection "fees" in this bill now being made available to the Secretary without further appropriation by Congress.

The CHAIRMAN. You may be interested to know that I was opposed to that bill.

Mr. PARLIN. In its outcome that is fine. Do you want me to go on?

The CHAIRMAN. Surely.

Mr. PARLIN. That is fine, Senator. We are in hearty accord with you in getting that one out.

The CHAIRMAN. I was referring to the previous legislation.

Mr. PARLIN. Yes. Thank you. We think you did a real service. We were asleep at the switch and did not do anything about it.

The CHAIRMAN. I held up the bill for 2 years and if I had had your support I might have been more successful.

Mr. PARLIN. You will have it from now on, from the magazines.

The CHAIRMAN. That is the trouble with you men, you are always awake on occasions.

Mr. PARLIN. Just let us know, Senator, when you want some help on this one and we will be there. [Laughter.] If you want one or if you want the whole 150 we will come down.

The CHAIRMAN. That is a promise?

Mr. PARLIN. Yes, sir; we will be there. We are all in accord. I guess we haven't anything to argue about except to go on and explain what this is all about.

With reference to these fees, two provisions are especially objectionable; first, the fees paid by manufacturers include cost of administration and cost of establishing additional definitions and standards. Under this provision, as we understand it, the Secretary with a small appropriation can establish grade A, grade B, and grade C for one product, let us say canned beans, and then make the reluctant volunteers for the voluntary inspection service pay the cost of inspection plus the cost of administration, plus repaying the cost of establishing the "additional standards". Having now got this original appropriation back, he may establish grades for a second product and so on indefinitely.

Thus under these provisions the Secretary may extend "voluntary inspection" throughout the entire food industry and build a huge bureaucracy, financing the operation by fees from reluctant manufacturers and with no opportunity for Congress to pass on appropriations. We believe that this huge expense should not be saddled on the food industry and we believe that Congress should not abrogate its power to control appropriations.

This "voluntary inspection service" is made to include "any manufacturer or packer of any food, drug or cosmetic", but section 12, authorizing "standards" (i.e., as we interpret it, grade A, grade B, and grade C), applies only to foods.

Hence, it appears to us that the primary intent of the "voluntary inspection service" section is to authorize the Secretary to establish grade A, grade B, and grade C in foods.

While the service is called "voluntary", it is in fact virtually compulsory if the Secretary cares to make it so. In view of the publicity and inspection and seizure powers vested in the Secretary, no manufacturer would dare long to hold out against the wish of the Secretary that he submit to "voluntary inspection."

Even if the Secretary did not coerce canners and manufacturers, there probably could be found in every line a certain number of weaker manufacturers who would apply for the service in order to get the sales advantage of a United States guaranty of their grades backed by the "publicity" power of the Secretary.

In the face of this Government-sponsored publicity, others would feel obliged to follow, with the result that we would have an enormous bureaucracy of inspectors and their supervisors—the more the merrier, since paid for by the canners and manufacturers—in other words, by reluctant volunteers. How vast this bureaucracy might become may be inferred from the fact that in "foods" as designated in the bill there are, according to the census of manufactures, more than 45,000 plants. All this will increase the cost of packing and manufacturing and this cost must in the end come out of either the grower or the consumer.

We strongly object to the section as it stands for six reasons:

1. Foreign to title.

We object, first, to the grading plan because it is wholly foreign to the title. The title deals with adulterated or misbranded foods, drugs and cosmetics; false labeling and false advertisement. This plan has no relation whatever to public health. Minimum grades may have justification on the grounds of health, but grades above minimum standard have no relation to public health and never should have a place in this bill.

By no stretch of the imigration can one find authority in the title (outside of the words "for other purposes") for establishing grade A, grade B and grade C and for using Government publicity to urge people to buy by these grades instead of by advertised brands. The title gives no hint of a bureaucratic control of the entire food, drug and cosmetic industries and of the advertising industry as well (so far, at least, as advertising in these classifications is concerned).

2. Not seen in cursory reading.

We object to the grading plan, second, because such a grading plan cannot be found by a cursory reading of the Bill and is entirely different from what many people have understood from Professor Tugwell's——

The CHAIRMAN. By the same token, Mr. Parlin, I suppose a lot of other things could be read into the bill.

Mr. PARLIN. That is what I am afraid of. We want you to rewrite it, Senator. We think after you have rewritten it we will come down here to talk for it. Do you wish me to go on with my argument?

The CHAIRMAN. Go ahead.

Mr. PARLIN. I would like to tell you what is the matter with this as we see it.

We object to the grading plan, second, because such a grading plan cannot be found by a cursory reading of the bill and is entirely different from what many people have understood from Professor Tugwell's exposition of the section to be the significance of the provision.

Professor Tugwell, in a press release, said:

> The most important provision of the Copeland bill from the standpoint of the food industries is that it provides for the formulation of food standards having the force and effect of law. The McNary-Mapes amendment to the foods and drugs act provided for such standards for canned products only. S. 1133, approved by the Department of Agriculture and also introduced by Senator Copeland some 2 years ago was designed to extend this same authority to establish standards for all food products, but it failed of passage. The new Copeland bill contains this as a provision.

From this one might naturally infer that the bill merely extends the application of the McNary-Mapes amendment to additional products but, as a matter of fact, the bill provides for something very different from that.

The McNary-Mapes amendment provides for minimum standards and requires packers who put up goods below the minimum standard to label their goods substandard. To this no objection is offered. But this bill says "standards" not "minimum" standards. To this we strongly object.

3. Unenforceable.

We object to the grading plan, third, because the provision for grading is unenforceable. Competent attorneys are agreed that such provisions are unenforceable. The difference between grade A and grade B is largely a matter of judgment and to try to put a man in jail for putting grade A on a can where the secretary thinks it

should be grade B, can produce only a hopeless mess. Possibly you could convict a man for putting grade A on his can if he consistently put up only grade C products. I do not believe you ever could convict a man for using grade A if his product consistently was grade B or even if it were occasionally grade C.

If passed, the secretary will have three courses before him—all of them bad:

(1) Try to make every one live up to his—that is, Secretary of Agriculture's—idea of what grade A means, which will involve no end of litigation.

(2) Be lax in enforcement, letting the unscrupulous induce the public by a grade A label to think the quality of their goods superior to what they are.

(3) Be partial—that is, use litigation as a threat against those who de not accept his "voluntary inspection service."

4. Would injure consumers.

We object to the grading plan, fourth, because the grading provision would injure consumers by grading down.

The Secretary cannot by edict control the quality of a crop either in 1 year as compared to another, or as to normal differences in various sections of the country. He will have to make grade A low enough so that practically all canners in all seasons in all parts of the country can get a consequential part of their crop under grade A. The practical effect of grade standards would be a grading down to the minimum set for each grade.

5. Would threaten existence of newspapers and magazines.

We object to the grading plan, fifth, because the plan for food standards accompanied by "voluntary inspection" and "publicity" threatens the very existence of newspapers and magazines.

The plan proposes to substitute government grades for advertised brands and to substitute government publicity for manufacturer's advertising. The immediate objective is to apply this to food advertising, the next step presumably is to apply the plant to drugs and cosmetics which are already included in the voluntary inspection provisions and the ultimate aim, I presume, is to apply the plan to all advertising.

Newspapers and periodicals quite universally are sold for less than they cost; they depend upon advertising revenue not only for their profits but for their existence. So essential is this advertising revenue that a loss of even a minor percentage of their advertising revenue would put most publications in the red, and the loss if long continued would force many newspapers and magazines into bankruptcy.

In a brief to the N.R.A., the periodical publishers presented evidence that approximately 90 percent of the periodical publishers were operating in the red. They showed that unlike most industries it would be impossible for them to pass increased labor costs along to others. However, they agreed to accept the burden of increased labor costs in the hope that N.R.A. would bring them increased advertising revenue.

If on top of those increased labor costs, this Bill, especially through this grading provision, brings them material loss of revenue, they are ruined.

In this situation, you face not an academic question of whether government publicity is preferable to commercial advertising; you face the hard and alarming fact that the operation of these provisions would be quite certain to throw many publications into bankruptcy.

The whole American system of merchandising and of publishing is based on manufacturers' advertising.

In a letter to Edgar Kobak, president of the Advertising Federation of America, President Roosevelt said—we quote from that letter:

THE WHITE HOUSE,
Washington, June 15, 1933.

Moreover, I wish you would say that I hope the high standards which have made good advertising an economic and social force of vital importance to us all will be continued. Your cooperation will be valuable to the restoration of improved levels and flow of trade. It also will help business and industry to return to better times. By doing these things you will be serving your country and Government.

FRANKLIN D. ROOSEVELT.

In a letter sent September 29, to leading manufacturers and advertisers throughout the United States, Gen. Hugh S. Johnson said:

Aggressively promote your products to the public.

There is no longer any reasonable doubt that the public is beginning to shop again, and to look toward replacements for its wornout possessions.

American industry must help the public to find the goods it needs.

The modern method is advertising. The American public looks to advertising for news of good merchandise and good values.

There has never been a time when the public was so alert for news as now. Events have moved so rapidly that people would be completely ignorant of what is going on if they did not closely follow the press.

This tremendous public interest in news can be capitalized by American industry. And the way to do it is to place the news about a good value or a good product side by side with the other news of the world.

The canned goods industry has been builded by manufacturers' advertising. Before manufacturers' advertising, many people believed products in tin cans were poisonous. The advertising of Campbell, of Heinz, of California Packing Corporation, of Libby, McNeill & Libby, and of many other manufacturers, wholesalers, and retailers have builded great markets for canned soup and beans and fruits and vegetables, creating thereby large markets for farm products. It is this advertising which, under the grading plan, is the first subject of attack. If advertising in these lines be curtailed, it is inevitable that markets will decline and growers as well as canners and publishers will suffer.

For any legislation which will curtail this type of advertising, the publishers of the United States, I feel safe in saying, are unanimously and strongly opposed.

6. Will injure the recovery program.

Finally, we object to Senate bill 1944 because we believe it would work against the success of the national recovery program.

Senator MCNARY. Is that the Copeland bill or the Tugwell bill you are talking about now?

Mr. PARLIN. I am still talking about the Tugwell bill, if you call it that. I don't know what you call it. That is what we call it. We insist on calling it that. [Laughter.]

Now, we are still objecting to these provisions which would produce that which is the proposition of standards. We have no objection at all to your McNary-Mapes amendment; that is all right. We will not come down and say one word. You will never find us opposing that. Extend it as far as you want.

The only thing we are arguing against is to establish a minimum standard and establish 3 or 4 or 44 or any other standards above it and try to enforce them.

Finally, we object to these provisions because we believe it would work against the success of the national recovery program. The publishing industry itself employs more than 100,000 workers and any shrinking in advertising revenue will throw many out of employment. Furthermore, the publishing industry uses several hundred thousand tons of paper and many thousands of tons of ink.

Publishers will buy less paper, less ink and less of other supplies and thus additional thousands now employed in making paper, in making ink and other supplies are likely to be thrown out of work.

But more serious than either or both of these facts, business will lose its stimulation; sales for advertised brands of food, we believe, will decline; farmers and growers, we believe, will find their markets curtailed; many now employed in the food and farming industry are likely to be out of work. The total unemployment resulting from the bill are likely to run into tens of thousands and again may I say that while many will have suffered no one will have benefitted.

May I add that in my opinion no government publicity directing the public to buy foods by grade A, grade B and grade C can compensate for a lessening or discontinuing of manufacturers' food advertising with the appetizing displays of its color pages.

This is a time when we need to rebuild American prosperity. Manufacturers' advertising is a prime essential to expedite the movement of goods, to enable the reemployment of idle men and to stimulate prices for farm products. The provisions in this bill for grading and for voluntary inspection work are against this purpose.

In our opinion they are the most dangerous provisions in the bill. We believe they would produce chaotic conditions in merchandising and in newspaper and magazine publicity.

If all other objectionable provisions in this bill were removed and the grading and voluntary inspection features alone were left, publishers will would be strongly opposed to the bill.

We strongly urge—

1. That authority to make food standards be limited to minimum standards.

2. That the voluntary inspection service be eliminated. If it is necessary to have some method or, rather, as was suggested, a laboratory for drugs or something, find another way to do it. Do not set up a bureaucracy that will keep itself up, get its own feeds, and never depend on Congress, and if it runs for a hundred years they would never have to go back to Congress to enforce it. You ought never to abrogate that degree of Congressional power.

3. That the publicity section—I am not very sure on this one; I am not very sure whether that publicity section carries with it the authorization to spend United States money for paid advertising to promote these grades. I have a little difficulty in reading it in, but I found this there after reading a long, long while, and I am not sure it is not there, and what I suggest is that we make it sure by putting an amendment in there providing that no Government publicity shall be spent for promoting the advertising brands or standards above the minimum standards.

The CHAIRMAN. You did not even give a cursory reading because you are a little doubtful. It was by a cursory reading that you found the other.

Mr. PARLIN. It was not a cursory reading. I told them I thought the bill was all right the first time I read it, and after I read it the third time I had a few doubts, and now I am down here to tell you we think it is the most vicious bill from the standpoint of the advertising business that was ever concocted.

The CHAIRMAN. Mr. Parlin, please don't read it again because you would shoot the author at sunrise.

Mr. PARLIN. I am not a man of personal violence myself. I will leave that to the others.

Now, we have in addition to this gone through this bill section by section for particular objections. Some of these you might say were out of our realm, but, as a matter of fact, everything is in our realm because anything that adversely affects manufacturers adversely affects us, and, hence, I think we would be competent to offer testimony on that ground on anything here, but we will just file that because most of them have been covered, and I do not think we need to go in there except that I would like to look at section 17 for a moment, the section on penalties. That begins on page 23.

We get into it on no. 2 there, which says:

> The receipt in interstate commerce of any food, drug, or cosmetics and
> 3. The dissemination of any false advertisements by radio broadcast, United States mails, or in interstate commerce for the purpose of inducing, directly or indirectly, the purpose of foods, drugs, and cosmetics.

I do not think we have any ground for objecting to being in there, but I will call attention on page 24 to section (d).

I am not one who ever lost any sleep thinking that the Secretary would refuse to call for the information and that we might get in jail. Some people get a little worried, but we did not; that is just one of the things that we will not do. [Laughter.]

But, meanwhile, there is one thing in here that causes me some worry. I am not an attorney, and I may be all wrong, and if I am wrong I will forget it. They cleaned up the wording of the section, and I have nothing to say about it except this:

By that provision No. 3 back there, as I understand it, if we disseminate a piece of advertising that is declared by a court to be false, we are then guilty, and that this merely exempts us from criminal prosecution, but leaves us still liable under civil prosecution. That is, if there was an occasion which somebody won a case where we had put an advertisement in there, any of our publishers, I am talking about the whole 150 of them, if any of us put an advertisement in there and the court decided that that was wrong, they would have the right to bring a civil suit against the publishers for running that. If so, I think we ought to be protected on that, but I do not know just how.

The CHAIRMAN. You would be liable now, would you not, without any kind of new law?

Mr. PARLIN. I assume that we have the general common law and statutory law of liability, and we have all got to face it now, but whether this makes a new one—the trouble with this one is that this would prove us guilty without our defense. They already went into court and proved it false, and we were not there, we were not a party

to it, and they found somebody guilty, and that is prima facie evidence that we were to blame, and they can start new suits all over the country.

I don't know what you can do about it, but I thought I would call it to your attention.

(Laughter.)

Now, there are one or two of these other provisions, such as the penalties, that I would like to speak of. I do not want to talk about there being too severe. We believe that, but somebody else has talked about it, and I will not bother you by taking your time on that.

Everybody realizes that in (b) that is too severe.

I believe, Senator, that no one ought to be prosecuted for running an advertisement until he has been warned that he is going to be prosecuted except in the most flagrant and most violent cases of endangering the public health. The man ought first be told that the product he is advertising, or the kind of copy he is using, is going to lead to prosecution if he does not quit.

The CHAIRMAN. That was suggested by a definite amendment.

Mr. PARLIN. That is fine. Thank you. I will say nothing more on that.

Now, this section (c) providing for a heavy penalty, Senator, should be eliminated, for this reason, that it makes test cases too dangerous. I have not heard anybody state that, and I do not know whether any one has. The judge has no option if the judge finds the defendant guilty, and he is going to be wilfully guilty to bring a test case—the judge has no option, he has to fine him $1,000 and send him to jail for 6 months. That shuts out test cases, and on any new legislation like this, we ought to get every opportunity for test cases.

May I also say just one thing about (e)? This says:

> No dealer shall be prosecuted—

This sounds all right if you cut out everything after "section", namely, "if he establishes a guaranty or undertaking signed by the person residing in the United States from whom he received the article of food, drug or cosmetic."

Now, there are 700,000 dealers affected by this, and just think of the 700,000 dealers—I suppose some of them have 10,000 items and maybe some have 30,000 in their stores. You may figure some way of getting the wholesaler to do this, but is it plain common sense to hold the dealer, and by the dealer I mean the wholesaler or retailer?

I am very cognizant of the fact that provisions similar to this were in the earlier act, but that does not answer the problem. I do not think it ought to be in the act. I do not think any dealer ought to stand the danger of being sent to jail for the crime of the manufacturer. He ought to take the responsibility of labeling his goods and marking them right, and unless the dealer willfully after notice continues to sell something injurious to the public health or contrary to the public morals, I think the dealer should be exempted.

If the dealers knew what the real significance of that is you would get so many wires you would not know what to do with them.

There is just one other phase to this, and that is its corporate matter in (b) on page 26. "Whenever a corporation"——

The CHAIRMAN. I want to call your attention to the fact that the matter you spoke of just now is in the present law.

Mr. PARLIN. I know it is, but I say that ought not to be in there.

The CHAIRMAN. That this would be a good law if we changed it?

Mr. PARLIN. Certainly—if we were going to amend the Food and Drugs Act we would get the poor dealer yet. Certainly you do not want to send some dealer to jail to make him conscious of the fact that he is subject to a jail penalty? He did not know it before but now it is just so much publicity he will probably find it out.

Now, on page 26 this paragraph (b) says:

> Whenever a corporation or association violates any of the provisions of this Act, such violations would also be deemed to be a violation of the individual directors, officers, or agents.

I do not know whether you ever sold advertising or not, but if you did you would know how easy it was for some of the directors to find an excuse to vote against advertising, and believe me they will do it. [Laughter.] If you need any further testimony I will call on all the advertising men here. Now, I believe that no director ought ever to be prosecuted unless his company has previously been officially notified that a continuance of the advertising of that product or that party is going to lead to prosecution.

The CHAIRMAN. This is the same as it is in the Securities Act, I expect?

Mr. PARLIN. Well, I guess they had enough trouble with that one, too. [Laughter.] I do not know; I am not in the security business.

The CHAIRMAN. I have heard some criticism of that act.

Mr. PARLIN. Yes; exactly.

You see, the problems that we are dealing with on this one is fear. No matter how well these people meant it is fear that stops us. The greatest thing that deters advertising, over everything else, is fear, and the greatest thing that can be done for advertising today would be an assurance quickly that these provisions that are really going to be bad against advertising are not going to appear.

Now, so far as the problem of protecting the public health is concerned, anything within the bounds of reason in the way of legislation against doing that which will injure the public health we are 100 percent for. We are not down to argue that, we are not down to find something about.

I have told our men, and I think everybody in the business agrees with it, that the worst thing that could happen to us would be just to get no bill at all, just get this killed and nothing else. That is the last thing we want. We want the danger of this thing cleaned up; we will go 100 percent with you. Every publisher in our list, I believe, will go 100 percent with you in cleaning up the things that are the real purposes of the bill, and the only things we object to in the bill are, in the first place, the various grades and the extent of that authority—I do not need to talk of those; those have already been covered aptly. You have been very generous to me with your time. I do not know how much time you allowed me, and I probably took more than you gave.

The CHAIRMAN. You had just twice as much as we gave you.

Mr. PARLIN. That is fine. I certainly appreciate it, Senator. That was grand of you, and may I read just this much more?

We say that we all wish to promote the President's policy of getting men back to work, increasing farm prices, and restoring prosperity.

We realize the great opportunity that advertising can perform in this program, and we hope that nothing will be done to discourage legitimate advertising.

Thank you.

The CHAIRMAN. We are very much obliged to you.

I notice Mr. Robert Lynn is a member of the N.R.A. Consumers' Advisory Board. Regardless of what his testimony might be, I should like to ask Mr. Lynn if he would be good enough to tell us whether in his opinion this proposed legislation is counter to the efforts and practices of the N.R.A.

Mr. Lynn?

STATEMENT OF ROBERT LYNN ON BEHALF OF THE N.R.A. CONSUMERS' ADVISORY BOARD

Mr. LYNN. I have been summoned over here somewhat hurriedly from a meeting of the Consumers' Board of the N.R.A. I do not speak for that Board because I am speaking only as a member of that Board.

In addition to being a member of that Board, I happen to be the chairman of the Board's committee on consumers' standards.

I have been asked to come over and talk briefly as to whether the Food and Drug bill proposed is contrary to the N.R.A. as the consumers see it in the N.R.A. Administration. I have jotted down some notes that I will read here.

This point of view that the Food and Drug Act proposed is contrary to the spirit of the N.R.A. for the following reasons. N.R.A. codes are codes of fair competition.

Now, fair competition today, in view of our elaborate fabrication of commodities that we buy, in view of the use of synthetic materials, in view of the widespread use of packaging, necessarily must include competition in terms of quality as well as competition in terms of price.

The Agricultural Administration has found that in its milk agreements, for instance, in order to quote prices at all it must first set up standards as to butter-fat content.

In nearly every line of merchandising a similar need exists for quality standards on which and around which to build price competition.

Second, the importance of quality definition in the N.R.A. codes is attested by the fact that some producers and growers have actually come to the Code Authorities in the drafting of the codes and have asked for the establishment of quality grades and standards as parts of the codes.

Among the agreements that have already gone through, such expressions have come and have been incorporated for the following groups: The Citrus Fruit Agreement, the California Rice Mills Agreement, the Southern Rice Mills Agreement, and the California Cling Peach Agreement.

Third, N.R.A. is directed squarely at the stabilization of the industry. Among other things this necessarily entails, does it not, the curtailing of chiseling, cheap substandard grades.

Again, N.R.A. is interested in increasing the buying power, which means that current wages and losses in family buying power, due to mistaken substandard buying, must insofar as possible be raised and all possible buying power channeled into commodities that represent honest quality value and use value to the consumer purchasing the commodity.

Both the Government and industry is required as standard practices to buy, not by style and price, but by quality specifications, through this procedure they save many millions of dollars annually. There has never been an estimate of just how much the saving is, but it is so substantial that by buying by standard segregations is the accepted practice today.

If the N.R.A. stands for fair competition, we consumers submit that fair competition means giving our 30 million families, spending at the 1929 level 60 percent of our total national income over the retail counters of this country, the same kind of chances that government and industry now have to know what they are buying.

The consumer has historically been the man nobody knows here in Washington. For the first time, in the N.R.A. and in the Agricultural Adjustment Administration, the Government is recognizing that labor and the consumer and industry are joint partners in the industry of this country. This recognition has taken the form of definite administrative arms in the Recovery Administration.

Fair competition today means, therefore, not merely, as in the past, fair competition against another industry or merchant, but fair competition against this newly recognized partner in industry, the consumer.

The Food and Drugs Act, like the quality standards going into many of the recovery codes, represents a simple and inescapable necessary aid to the isolated consumer in his difficult and otherwise largely helpless effort to compete on equal footing with the vast resources of industry.

One final point: In urging support of the truth in advertising section of the new Food and Drugs Act, the consumer is simply bringing back to you business men and to advertising men the thing that for 20 years you have been talking about so proudly in printers' ink and elsewhere, the simple, plain fact of truth in advertising.

The CHAIRMAN. Thank you very much.

Bad as it is, I am glad this bill does not run counter to the N.R.A. as interpreted by Mr. Lynn.

May I ask Mr. Thomas Elliott, associate counsel of the Department of Labor, to say a word?

STATEMENT OF THOMAS ELIOT ON BEHALF OF THE DEPARTMENT OF LABOR

Mr. ELLIOTT. Senator, I am appearing on behalf of the Department of Labor, not to argue for any specific provision in this bill, but generally to endorse the measure and to state that the Department regards as unsound the argument against the bill that if it were enacted it would adversely affect the workers of the country.

It is our belief that any temporary dislocation of employment resulting from the closing down of concerns unable or unwilling to comply with the law, would be more than compensated for, first, by the eventual increase of employment in industry for the manufactured products in which the public can have confidence; and, second

because the average wage earner has very little money to spend and this bill, if enacted into law, will help him to keep from being misled into wasting that little upon products which are useless and are actually harmful.

The CHAIRMAN. Thank you very much, Mr. Elliott.

[Applause.]

The CHAIRMAN. We have another 5-minute speaker, John A. Benson, of New York, president of the American Association of Advertising Agencies.

Mr. BENSON:

STATEMENT OF JOHN A. BENSON, ON BEHALF OF THE AMERICAN ASSOCIATION OF ADVERTISING AGENCIES

Mr. BENSON. As president of the American Association of Advertising Agencies, I represent a substantial cross section of advertising agency opinion, in appearing at this hearing to protest against the so-called "Tugwell bill", in its present form, confining my objections to its advertising provisions.

May I say at the outset that the advertising agencies are heartily in favor of giving the consumer and the public all needful protection against false advertising, and against the promotion through advertising of any bad drugs, adulterated foods, or dangerous cosmetics. We are deeply concerned about the consumer. She is our customer; upon her confidence depends the permanent success of any advertising effort.

Many of us feel that the present Food and Drugs Act, and other legislation now in effect, inadequately protect the consumer in these respects, and that additional legislation is needed, which should take the form of an amendment to the present Food and Drugs Act, without repeal.

False advertising of food, drugs, and cosmetics might be even more harmful than false labeling, since people read advertisments more freely than they read labels and are more influenced thereby.

But a distinction should be made between the requirements of a label and the requirements of advertising, in any legislation which may be enacted. The former is a factual statement of ingredients and uses; the latter is a persuasive appeal to the consumer, a selling argument to induce him to purchase. Hence, in the latter much more leeway is needed in the way of emotional appeal and dramatic presentation. You can construe a label narrowly and literally; but you have to construe an advertisement broadly in the light of its only function, which is to sell. And as a further difference, it is impractical to censor advertising in advance, because of its newsy character. That would practically blockade it.

It thus becomes evident that in adopting the language of a Supreme Court decision regarding labels, in its definition of false advertising, the Tugwell bill is in error.

It is comparatively easy to judge a label. Advertising is something quite different. It cannot be a cold statement of facts only; it must make an appeal to the emotions which motivate common, everyday action of people, such as the love of health, of personal beauty, of children, of effective vigor in the battle for success. There must be room for honestly imaginative appeal in portraying, as the case may

be, personal beauty, pleasure, or relief, to arouse the consumer's interest in the product and its use.

Advertising is a special plea; it is not a judicial analysis; it is salesmanship in print. This does not preclude an honest presentation of the value and effectiveness of a product. No advertiser, of course, has any right to be deceptive or to make literal truth a vehicle of falsehood by distortion of details in themselves true. His statement must be essentially true in material respects which are capable of harm to the reader or user of a product.

If an advertiser is not enthusiastic about this product, full of confidence in its worth, he might as well save his money. He must reflect that feeling. Everybody is biased in favor of his own baby, and should be expected to praise his own product. That is mere trade puffery, and has been recognized by the Supreme Court as in no sense a falsehood, even though it may idealize a commonplace or be overoptimistic.

Should such questions be entrusted entirely to any bureaucrat, however honest, who is unfamiliar with the true needs of advertising, as well as with its service to the consumer, or not in sympathy with such needs?

I would like to call the committee's attention to some provisions in the proposed Tugwell bill about advertising, and protest against their present form.

In section 9, (b) (1): An advertisement of a drug shall be deemed to be false if it includes "the name of any disease for which the drug is not a specific cure but is a palliative, and fails to state with equal prominence and in immediate connection with such name that the drug is not a cure for such disease."

There is no better instance of how the bill works against the consumer's interest than provisions of this kind requiring a "No cure" headline or signboard to be inserted on the label and in the advertising.

This would inevitably cause mistrust of the drug itself. People do not casually distinguish between a cure and a palliative. If it is said to be no cure, it will be offhand regarded as no good. Faint praise will damn anything. An obtrusive headline of this sort would violate the most elementary principle of advertising in repelling the reader before he gets into the text.

People would thus be discouraged from using a palliative which might be very beneficial to them, in relieving pain, in arresting disease, in removing irritation, or in making the sufferer more comfortable. This would be a distinct injury to him.

When you consider that there are only very few specifics recognized by the Government as having a curative effect, it is apparent that the great bulk of effective and meritorious drugs would have to be labeled "No cure", under the Tugwell bill as now written, and their advertising be emasculated.

In section 9 (b) (2): An advertisement of a drug shall be deemed false if there is "any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion."

How often is there any general agreement of medical opinion as to the effect of a drug, and who shall determine when it exists? Doctors differ widely in their treatment of disease and in their estimate of drugs as curative agents. There are even opposing schools of thought.

because the average wage earner has very little money to spend and this bill, if enacted into law, will help him to keep from being misled into wasting that little upon products which are useless and are actually harmful.

The CHAIRMAN. Thank you very much, Mr. Elliott.

[Applause.]

The CHAIRMAN. We have another 5-minute speaker, John A. Benson, of New York, president of the American Association of Advertising Agencies.

Mr. BENSON:

STATEMENT OF JOHN A. BENSON, ON BEHALF OF THE AMERICAN ASSOCIATION OF ADVERTISING AGENCIES

Mr. BENSON. As president of the American Association of Advertising Agencies, I represent a substantial cross section of advertising agency opinion, in appearing at this hearing to protest against the so-called "Tugwell bill", in its present form, confining my objections to its advertising provisions.

May I say at the outset that the advertising agencies are heartily in favor of giving the consumer and the public all needful protection against false advertising, and against the promotion through advertising of any bad drugs, adulterated foods, or dangerous cosmetics. We are deeply concerned about the consumer. She is our customer; upon her confidence depends the permanent success of any advertising effort.

Many of us feel that the present Food and Drugs Act, and other legislation now in effect, inadequately protect the consumer in these respects, and that additional legislation is needed, which should take the form of an amendment to the present Food and Drugs Act, without repeal.

False advertising of food, drugs, and cosmetics might be even more harmful than false labeling, since people read advertisments more freely than they read labels and are more influenced thereby.

But a distinction should be made between the requirements of a label and the requirements of advertising, in any legislation which may be enacted. The former is a factual statement of ingredients and uses; the latter is a persuasive appeal to the consumer, a selling argument to induce him to purchase. Hence, in the latter much more leeway is needed in the way of emotional appeal and dramatic presentation. You can construe a label narrowly and literally; but you have to construe an advertisement broadly in the light of its only function, which is to sell. And as a further difference, it is impractical to censor advertising in advance, because of its newsy character. That would practically blockade it.

It thus becomes evident that in adopting the language of a Supreme Court decision regarding labels, in its definition of false advertising, the Tugwell bill is in error.

It is comparatively easy to judge a label. Advertising is something quite different. It cannot be a cold statement of facts only; it must make an appeal to the emotions which motivate common, everyday action of people, such as the love of health, of personal beauty, of children, of effective vigor in the battle for success. There must be room for honestly imaginative appeal in portraying, as the case may

be, personal beauty, pleasure, or relief, to arouse the consumer's interest in the product and its use.

Advertising is a special plea; it is not a judicial analysis; it is salesmanship in print. This does not preclude an honest presentation of the value and effectiveness of a product. No advertiser, of course, has any right to be deceptive or to make literal truth a vehicle of falsehood by distortion of details in themselves true. His statement must be essentially true in material respects which are capable of harm to the reader or user of a product.

If an advertiser is not enthusiastic about this product, full of confidence in its worth, he might as well save his money. He must reflect that feeling. Everybody is biased in favor of his own baby, and should be expected to praise his own product. That is mere trade puffery, and has been recognized by the Supreme Court as in no sense a falsehood, even though it may idealize a commonplace or be overoptimistic.

Should such questions be entrusted entirely to any bureaucrat, however honest, who is unfamiliar with the true needs of advertising, as well as with its service to the consumer, or not in sympathy with such needs?

I would like to call the committee's attention to some provisions in the proposed Tugwell bill about advertising, and protest against their present form.

In section 9, (b) (1): An advertisement of a drug shall be deemed to be false if it includes "the name of any disease for which the drug is not a specific cure but is a palliative, and fails to state with equal prominence and in immediate connection with such name that the drug is not a cure for such disease."

There is no better instance of how the bill works against the consumer's interest than provisions of this kind requiring a "No cure" headline or signboard to be inserted on the label and in the advertising.

This would inevitably cause mistrust of the drug itself. People do not casually distinguish between a cure and a palliative. If it is said to be no cure, it will be offhand regarded as no good. Faint praise will damn anything. An obtrusive headline of this sort would violate the most elementary principle of advertising in repelling the reader before he gets into the text.

People would thus be discouraged from using a palliative which might be very beneficial to them, in relieving pain, in arresting disease, in removing irritation, or in making the sufferer more comfortable. This would be a distinct injury to him.

When you consider that there are only very few specifics recognized by the Government as having a curative effect, it is apparent that the great bulk of effective and meritorious drugs would have to be labeled "No cure", under the Tugwell bill as now written, and their advertising be emasculated.

In section 9 (b) (2): An advertisement of a drug shall be deemed false if there is "any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion."

How often is there any general agreement of medical opinion as to the effect of a drug, and who shall determine when it exists? Doctors differ widely in their treatment of disease and in their estimate of drugs as curative agents. There are even opposing schools of thought.

Basing such a determination on any general agreement, as interpreted by the Secretary, would leave a wide-open field for error and one-sided opinion. It might also handicap Government in obtaining convictions.

If any criterion is needed, it should be something more definite and concrete, such as an accepted scientific and clinical test. But why should there be any criterion set up in advance? The courts have always been able to judge of expert testimony offered by either side, in medical as well as other fields.

In this connection it should be remembered that the infraction is a criminal offense, entailing severe punishment, and should conviction depend upon anything as vague and variable as general agreement of medical opinion?

In section 9 (c): To discourage self-medication, the bill prohibits claiming in an advertisement that a drug has any effect upon a list of mentioned diseases, many of them common and commonly treated by physicians, with the same or similar products.

Again the sufferer is deprived of having suggested to him, through advertising, palliatives used by physicians themselves.

If any effect were changed to read "any curative effect", it would give the consumer all the protection needed and not deprive him of suggested palliatives of substantial benefit to him.

Such claims are not prohibited if made in a scientific journal, appealing to doctors and pharmacists. Why should the sufferer himself be barred?

The Secretary is authorized to add to or subtract from that list of diseases, as he may see fit. That seems like unwarranted authority which should be exercised only on recommendation of a scientific body, with appeal to the courts.

In section 21, the Secretary is himself directed to do a form of advertising which might easily be false and very harmful to legitimate business, in the following paragraph:

> The Secretary shall cause to be disseminated such (adverse) information regarding any food, drug, or cosmetic as he deems necessary in the interests of public health and for the protection of the consumer against fraud.

It seems to us this should be permitted only in case of imminent danger to public health, and then after a hearing, and in all other cases should not be permitted until after fraud or violation of the act has been admitted by the offender or established in a court of law.

This is one of the most despotic features of an autocratic law; it would put into the hands of the Secretary a coercive power to undermine or ruin a business. Subsequent correction or reparation might be helpless to undo the harm. No man is wise enough to be entrusted with such power.

And the Secretary is not only empowered to do this; he is directed to do so.

In section 23, (c): It is provided that in hearings authorized or required by the act, the findings of fact by the Secretary shall be conclusive if in accordance with the law. This, we understand, will be changed by the sponsors of the bill—but it suggests a question as to how the Secretary will arrive at advertising judgment.

We feel that all advertising questions not involving fraud or the promotion of dangerous products, should be referred to responsible

channels of experienced opinion in the advertising industry itself. If the Secretary is given power to make such decisions, they should be based upon the findings of such a judicial-minded body, just as physiological and therapeutic questions should be referred to a scientific group.

This is a form of that self-regulation which the Government is fostering through the N.R.A., and should be contemplated or provided for in any legislation enacted regarding advertising. The advertising and publishing industry has already built such a body of opinion now ready to function.

In its definition of a false advertisement, the bill is altogether too vague and unsafe. It states in section 9 (a):

> An advertisement of a food, drug, or cosmetic shall be deemed to be false if in any particular it is untrue, or by ambiguity or inference creates a misleading impression regarding such food, drug, or cosmetic.

According to this provision any harmless "puffing" or slight or inconsequent or fanciful variation from literal truth would constitute a false advertisement, as would also be true if a statement seemed ambiguous to any reader however unintelligent or prejudiced, or should deceive him by making a wrong impression upon his mind.

No statement, it seems to me, should be held responsible for inferences drawn from it by any state of mind of the reader. He might be a moron or biased, full of morbid fears or fixed ideas. What he might make out of a perfectly sound and true statement, nobody can control.

A statement is either true or it is false in itself; that is a question of fact; it is not a question of what anybody might think or infer.

Of course the details of a statement may be literally true and still make a misleading impression by arranging such details in false perspective. That should be included as deceptive advertising.

Would the following statement not be equally effective in protecting the reader without handicapping honest advertising?

> An advertisement of a food, drug, or cosmetic shall be deemed to be false if in any material respect it is essentially untrue or inherently deceptive.

I believe the advertising agency group which I represent would also endorse the definition of false advertising made by Mr. Charles Wesley Dunn this morning in his address on behalf of the Grocery Manufacturers, as follows:

> An advertisement of a food, drug, or cosmetic shall be deemed false if it is false or injuriously deceptive in any material particular related to the purposes of this act.

Section 17 (6) (d): Does not clearly exempt media owners and advertising agencies from liability for infraction and hold the advertiser solely responsible, as should be done and is intended to be done. Paragraph (d) of section 17, exempts the media owner and advertising agency "if, on request of an officer or employee duly designated by the Secretary, he furnishes the name and post-office address" of the advertiser. In event the Secretary did not choose to request this information, there would be no exemption. The provision should be so written that exemption should always apply unless the media owner or the advertising agency declined to furnish such information, if known, and on request.

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The advertiser himself should be solely liable for false advertising, because he alone is always in possession of the facts and can authorize publication of the advertisement. The responsibility is his.

The responsibility of the advertised product, by a reputable firm in a responsible magazine, is the consumer's best safeguard against inferior products or false claims about them; and any unnecessary handicapping of sound advertising by rigid methods of interpretation, in order to catch a small minority of offenders, would work an injury to the consumer.

It is vital to the best interests of advertising and to its ability to serve the consumer that no legal restriction of advertising be so worded as to obstruct or emasculate legitimate and honest appeal. There should be no vague borderland of ambiguity or inference which might or might not be regarded by someone as untruth. Only essential truth or falsity should be in question—inherent in the statement itself.

Otherwise there is bound to be a widespread discouragement advertising by honest concerns afraid to venture into an undertaking which would expose them to failure through ineffective appeal, on the one hand, or lawbreaking, on the other.

A serious slump in advertising would inevitably slow down business at a time when stimulation is critically needed, and might inflict disastrous harm upon the publishing and advertising interest. Especially would this be felt among the thousands of small-town newspapers now already in distress, so dependent for volume upon food and drug advertising, constituting over 50 percent of all advertising volume. It might bankrupt the weak and weaken the strong to a degree which might easily undermine the editorial and news independence of this major arm of the country's press.

The Department of Agriculture, in our opinion, is interested in protecting the public health. It is not interested in regulating advertising per se or the ethics of advertising, beyond the underlying purpose of the act; to protect public health.

It might do more harm than good, to carry out this major purpose in any way which discourages or obstructs the honest advertising of a worthy product.

The great bulk of advertising of food, drugs, or cosmetics, falls within that designation. It is helpful to consumers in bringing to their attention wholesome food values and their economical or appetizing use; safe home remedies and their beneficial application; cosmetics skillfully designed and compounded to improve appearance without deleterious effect.

These products and their advertising should not be handicapped by restrictions applicable only to a few violators of good faith or public health. Any legal effort to catch them should be so safeguarded by clear definitions of dishonesty and dangerous effect as to sift out the guilty in advance and exempt all others.

There is something else behind this question, fundamental to public welfare, and that is distribution.

The propelling force behind that is advertising. You cannot check the one without slowing down the other. Advertising is commercial news, as potent in its field as the daily press. There is no substitute for it. Just as news, to be influential, must be interesting and written to at once arouse interest and then satisfy it—so advertising must

give the public an incentive to read about products and then to use them.

No dry statement of fact could do that. No mere analysis of ingredients or their technical application would suffice. The most authoritative appraisal of them by Government itself, would leave the reader cold, uninterested, and unimpressed by the worthiest product if presented without emotional glamour, or the promise of personal benefit, which is the life of advertising.

People respond to advertising because it is like life itself, full of human incentives to get on in the world, be comfortable and have pleasure.

People want, and will always want, their information about merchandise in the cheerful, inspiring, and optimistic mood of advertising. There is no substitute for that. They want to feel that a given product will do something to make life brighter and better—more endurable and less drab—for themselves and their children. That's half the fun of owning and using, of striving and earning.

The influence of advertising is enormous in these respects. It induces effort, raises the standards of living, sustains courage, keeps a brimming tide of merchandise flowing from producer to consumer.

And advertising would fail and shrivel if you dispelled its pleasing aspects, its emotional appeal, its cheerful promise of a better, brighter or easier way—all within the limits of worthy goods honestly presented.

No government can afford to tamper with that force. It runs through the human heart. It moves the human will. It idealizes a world of things. Those who look upon this force as waste must think the same of life itself with all its vanity, hope and aspiration motivating progress.

The value of advertising to the consumer as well as to the producer might be seriously impaired if the Tugwell bill by implication or inference authorizes the Secretary to make Government classifications of quality and grade of foods, based on analysis and inspection, and then himself advertise those grades to the public.

Doing so might discourage producers from advertising their own brands and trade-marks, upon which millions of consumers have come to rely in their choice of food, and thousands of factories have come to depend for moving their output. The latter might lose much of their incentive to pack a fine product, if the Government grades prevailed. There would be much less consumption, without the inviting appeal of advertising. The food industries would suffer.

While many consumers might be guided by Government standards in their purchase of food, they would not be encouraged to purchase, take no pleasure in choosing their favorite brands. Government appeal would have a deadening effect upon them and upon trade. People do not want to be regimented in their purchases any more than they want to be regimented in any other respect. They want liberty of selection through the inviting and attractive appeal of the printed word.

Advertising would still persist, of course, because people want it; but it would be seriously impaired by Government competition.

Fixing minimum standards or grades would be a safeguard to the public, without interfering with the advertising of brands or slowing down of the demand for meritorious food. There could be no objection to that.

The CHAIRMAN. The next speaker is Mr. William L. Daley, Washington representative of the National Editorial Association.

STATEMENT OF WILLIAM L. DALEY, WASHINGTON REPRESENTATIVE OF THE NATIONAL EDITORIAL ASSOCIATION

Mr. DALEY. My name is William L. Daley, and I am the Washington representative of the National Editorial Association.

I am appearing on behalf of the National Editorial Association to protest the provisions of bill S. 1944, commonly called the Tugwell bill. Our association represents directly and by affiliates 12,000 newspapers located mainly in the smaller cities and towns of each of the 48 States. The association has been in existence for 50 years and during that time has been the recognized spokesman for several hundred small city dailies and all of the so-called country weekly press.

At the outset let it be understood that we believe that in the main some of the objectives of the bill are laudible. The plan in its present form is sufficiently spacious to raise grave doubts in our minds as to its practical aspects. Much of the testimony adduced before their subcommittee by previous speakers shows quite clearly that present laws are adequate or could be made effective by a few amendments in order to clear out any undesirable undergrowth that has cropped out here and there in the industries covered by this bill.

It would be foolhardy for the Congress, in its wisdom, to acquiesce in this proposition, which would place axes in the hands of one or two officials to be used at will and without any substantial legal checks. Much has been said by previous speakers about the prop that this affords to bureaucracy. I do not believe that there is any industrial or professional group which has more intimate knowledge of the workings of bureaucrats than small-town publishers and printers. It is only natural that in view of experience that the small-town press should resent any proposal that smacks of bureaucracy on any bill that will clothe Government employees with power to build up what may amount to vicious tyranny.

This bill would bestow on the bureaucrats the mechanism of power so that all their acts based upon their own ideas or whims would have a halo of legality under this proposed law. They are in a position to propose restraints on the ground of general interest, whereas, it might simply be a case of conflicting opinions between government experts and equally efficient technical men in the employ of private interests. Unlimited power entrusted to bureaucrats warps their judgment on the opinions they might have as normal citizens. It may be compared to what the notorious Max Weber, in a discussion upon municipal enterprise at the Vienna congress of the Verein fur Socialpolitik declared,

> I should think myself a very poor bureaucrat indeed, if I did not believe myself to know better than these blockheads what is really good for them.

We want little of this bureaucracy in America.

Professor Tugwell in one of his propaganda articles in behalf of this bill, appearing in a trade paper September 16, said, "By far the most flagrant abuses are found in * * * small dailies,

country weeklies." The professor pays his compliments to the majority of American newspapers in the declaration that—

> Many small-town newspapers salve their consciences for advertising perfectly worthless and often dangerous products by charging a higher advertising rate for this type of copy.

The Professor is apparently referring to the horse and buggy days of the newspapers and the advertising business. This unfair statement of this Government advocate greatly exaggerates the present day situation. Unfortunately he has been so busy fostering his pet theories that he has not taken the trouble to inquire into present practices. The rank and file of American newspapers, particularly in the small towns, are as zealous in guarding their columns against frauds as any ethical medical journal, for they have the same definite responsibility to their readers. Contrary of Dr. Tugwell's ideas that the average newspaper cannot curb its cupidity, as he inferred, we call your attention to the inescapable fact that it would be suicidal for a publication, which must depend upon the public patronage to be a party to a deal in which its readers are flim-flammed by fraudulent advertising.

The national and State organizations of newspaper publishers exercise the utmost vigilance in policing the columns of their member papers against fraudulent advertising. Every known fraud is reported in special bulletins and a warning sounded against the acceptance of advertising copy from these sources. As a consequence advertising valued at thousands of dollars is turned down because copy is questionable. However, I do not suppose that we should take Professor Tugwell's charges too seriously. It is an established fact that all crusaders and reformers would have it appear that those who disagree with them are besottedly selfish.

The reasons for our interest in this bill are obvious. Commodities affected represent substantial percentages of our advertising revenue.

We do not fear the bill because of the type of products represented in the "Chamber of Horrors" and paraded here yesterday, or any other product genuinely dangerous to health.

The reason we oppose the bill is that we believe that it adversely affects the interests of legitimate small-town advertising and the prosperity of the small-town and rural population on whose buying power the value of our advertising depends.

From the standpoint of its effects on the advertising of legitimate products we endorse the position of our advertising competitors, the magazine publishers. In fact, we feel that in certain respects our problem is more pressing than theirs. They are to some extent protected by long-term advertising contracts while much of our advertising is booked from week to week.

Volume national food and drug advertising in small-town newspapers: A study of six recent issues of the average small-town paper, both daily and weekly, shows that approximately 17 percent of the total lineage including local (other than classified, professional cards and public notices) is covered by advertising of commodities listed under the terms of this bill. It represents more than 25 percent of the total advertising revenue. To show you how greatly publications are interested permit me to give you a few citations. (See exhibit.)

Scare the national advertisers with the phrasing of the advertising clause and at a single stroke you reduce not only the national advertising of our members, but also the local advertising which represents a substantial portion of the income on which their very existence depends

Substitute the prestige of Government grading of food products for the advertised national brands and you further reduce the income of our members in the same two ways.

Many manufacturers of foods, drugs, cosmetics, and other products covered by this proposed bill use cooperative advertising. By cooperative advertising I mean that they sell their products to the retailers in the various communities and by mutual agreement defray a part of the advertising cost of copy placed with the local newspaper. It is a sales method that is known in newspaper and advertising circles as the "50–50 plan." At times, it is on an unlimited 50–50 basis; in other cases, a set amount is appropriated; some manufacturers are willing to set aside a percentage of the purchases of the dealers to be met by a like amount from the dealer and used for advertising in the local paper. New forms of competition are constantly creeping into the field to further divide the advertising dollar.

The cooperation of the small-town daily and weekly newspaper with the local merchant does not end with the publication of an advertisement. The local publisher encourages the merchant in his town to have window and counter displays hooking up with their weekly advertisements, particularly so when a nationally advertised article is being pushed. In other words, the publisher is interested in the ultimate success of the advertising campaign and not simply from a dollar and cent standpoint. It is our opinion, based upon surveys, that much of this cooperative advertising will be abolished if this proposed bill is enacted into law. If the local merchant cannot be assured that the manufacturer or distributor will assist him in paying his advertising bills for the sales promotion of products on his shelves then it is idle for the small-town publisher to expect this retailer to advertise to any degree in his local publication.

If the restrictions on adjectives and descriptive matter, as contemplated in this bill, are carried to a logical conclusion it is obvious that the writers of advertising copy in local newspaper offices or in the advertising departments of local merchants will have much difficulty in locating words in the dictionary, which will convey a meaning to the buying public as to the merchandise offered and at the same time keep them out of jail, if these words are objectionable to a few individuals in the Department of Agriculture. Small-town daily or weekly newspapers exist largely from the revenues derived from the sale of local advertising. National advertising, unless it has the so-called dealer hook-up whereby a portion of the expenses defrayed by the producer represents only a small percentage of the publisher's income from advertising.

It may not be apparent to you who are not continuously engaged with the business of advertising to what extent the prosperity of the farm is tied in with the continual appeal of advertising to the appetites of people in all sizes of towns, but you may feel certain that our membership has no doubts on that score. Reduce this appeal for canned fruits and vegetables and for other classes of food products and present over-production of farm products will be even greater than it is now.

Nor is it important from our point of view whether farmers do or do not realize this in advance of the fact. Reduce the demand for farm products, the prices which are paid for them and you will have struck a deadly blow at the buying power of not only the farm, but of all small-town people who exist by serving the farmer. On this buying power the value of our publications as advertising media is based.

Consequently we propose as have our competitors that the wording of definitions and false advertising be changed, that the setting of Government standards for food products be limited to the protection of the public health and that section 22 with its voluntary inspection service be stricken from the bill.

The small-town publisher interested in this distributor should not be responsible for conditions for which the manufacturer is directly at fault. The public is accustomed to complaining to dealers with the expectations that the complaint will be laid at the door of the producer. A dealer, like the ultimate consumer is influenced by the representations of the manufacturer or his accredited agents.

It is the repressive influence on legitimate advertising which the bill inspires to which we object.

Finally, the small-town publishers do not believe that economic conditions justify tampering with the existing laws on a wholesale scale. Advertising is a vital public force that is essential to recovery. There are more urgent legislative matters that deserve the full attention of Congress. The drastic revisions proposed here are by no means emergency matters. On the contrary, it is obviously a bold bid for more power. The Government's case is comparable to that other guardian of the public—the officious policeman who clubbed a friend and explained, "It 'taint because I hate ye that I beat ye, 'tis because I have the authority."

The CHAIRMAN. The women of this country are interested in this bill, and I have observed a number of women in the audience. Those here present want to hear from the women of our country. I want, first, to call on Mrs. William Dick Sporborg, of Port Chester, N.Y.

STATEMENT OF MRS. WILLIAM DICK SPORBORG, OF PORT CHESTER, N.Y.

Mrs. SPORBORG. Thank you, Senator.

The CHAIRMAN. Mrs. Sporborg is one of our leading citizens and very much interested in all of these matters of public concern and we are very much interested in hearing what she has to say in regard to this matter.

Mrs. SPORBORG. Mr. Senator and members of the Senate subcommittee, at the risk of being out of order, and since I am the first woman who has been permitted to appear in your deliberations here, I want to state and have it put in the records that I am sure that I voice the consensus of opinion of all men and women in this audience when I pay tribute to you, Senator Copeland, for your fairmindedness, your patience, and your good humor which has thrown out such a genial atmosphere during this hearing. [Loud and continued applause.] You have heard that I am a direct constituent of Senator Copeland of New York, but you are all indirect constituents of his and I am glad that your enthusiastic applause has proved that you do

feel the way I do about the fine atmosphere that he has created here and the spirit of fair play and impartiality that has characterized his conduct of this hearing.

I think that is something that means quite a bit to every one of us here, and it is something that should not be overlooked. I can observe, as we all can, by his keen questions and ready discernment that he is aware of the needs and desires of all persons who are present here and who have made them known in any way. For identification for the record, I am Mrs. William Dick Sporborg, of Port Chester, N.Y. I am here as a consumer, representing myself and as part of the public this bill is aimed to protect; I am here as a citizen interested in my Government, its laws and institutions and the technique of its political science; I am here as the chairman of the Greater New York Citizens Anticrime Committee, including among other concerns deep interest in laws that are reasonably written and reasonably enforceable so that once again this country might foster respect for law and order and not further lawlessness and corruption.

I wish to state at the outset, that I personally have no commercial interest in the manufacture or sale or distribution of any foods, drugs, or cosmetics which would be affected by this bill; not only that, but that there is no member of my immediate nor my distant family who has any commercial interests in any of them. I am speaking from the standpoint of a consumer, whom you have called the public—and whom you intend to protect by this act. If I have learned nothing else at this hearing—and I have learned much for I have been here from its very beginning yesterday morning, and I have not missed one minute of these interesting proceedings—I have learned that the best protection to the consumer is self-protection through self education which will take into consideration all the very fine testimony that has been brought out here during these two days' intelligent presentations at this hearing. [Applause.]

I have noted with considerable interest that all my predecessors at this hearing both today and yesterday—and all of them men—began their testimony, no matter of what nature, with the avowal that they were sympathetic to the general purpose of this bill.

As a matter of record I wish to state that I stand wholeheartedly behind both the general purpose and moral principle of the new suggested bill. I feel that I would be doing less than my duty to myself and others if I did not refute the statement made here earlier this afternoon by the representative of the New York Board of Trade—Mr. Ray C. Schlotterer—who said that he believed the present bill (the 1906 Food and Drug Act) is adequate for public protection and that there was no public demand for a newer, stronger law. Speaking not only for myself, but to my best knowledge and belief, I believe I represent the opinion of thousands, both men and women, in this country, when I say that a stronger bill than the one now existing is needed for the protection of the public. We need a new law which shall include cosmetics in its consideration. I believe the present law is inadequate for full public protection. I am interested in and want to see an act that will make it a crime for anyone to manufacture, distribute, or sell any food, drug, or cosmetic that is unsafe and dangerous, but, I want a law that is clear, definite, practical, a law that insofar as it is humanly possible is foolproof, a law that is reasonably enforceable and one that can be fairly enforced.

Since Mr. Campbell himself and you, Senator Copeland, who are both on record favoring the purpose of this bill, have stated both yesterday and today that you favor some amendments—Mr. Campbell yesterday even suggested a concrete one himself—I could do no better than follow your example. To that end while I am in favor of the general purpose of this Senate bill 1944, I would like to suggest five definite amendments:

1. I am opposed to that provision which mandates disclosure of quantitative formula to the public. Mr. Campbell yesterday in this connection quoted a Supreme Court case "holding that no manufacturer has a right to secrecy against a consumer who has the right to know what he is buying." That's right in spirit. But let's examine its practical application in this instance. I doubt if the average consumer—and I am one of these—would be really protected and would really want to know what he was buying if he did read the quantitative formula in detail on every label.

Without scientific or clinical examination or analysis—means for which the layman does not possess—little if any real information and therefore protection could be obtained by the average consumer if he did read it. What I, as a consumer, do want to know and what I hold it my right to know—is the knowledge of the effect of the contents. That is my only real protection. I do not know nor do millions of others what proportion of any drug or preservative passes the safety line. Therefore, I myself, and I belive there are hundreds of thousands more like me, do not read the detailed medical formulas. We want to know the effect of ingredients used, we want to know those which are dangerous and unsafe, we want the protection that direct knowledge of the effect of medication and food combinations and cosmetics that are deleterious to the average user. [Applause.] One moment, please do not interrupt me with applause, you are using my time and the committee's time. I believe I can be informed in plain understandable English when any drug or food or cosmetic is injurious and receive adequate protection without the necessity for disclosing full quantitative formula which might, as has been indicated at this hearing, lead to trade piracy or unfair competition. We women have been drafted by our Government in a movement to help restore economic recovery with its prime object the removal of unfair competition. What I do concretely suggest in this connection Mr. Chairman, since you have asked here for definite suggestions, is that quantitative formulas in detail should be required for confidential registration with a dependable source of governmental authority where there will be safeguard against undue or unfair disclosure of an honest trade secret, and where such governmental authority would be empowered to control and thwart the output if harmful before it is manufactured and control its distribution before any damage is done. That would be real consumer protection without unduly obstructing legitimate business. The wise consumer knows that in the long run legitimate business is its ultimate safeguard.

2. I suggest the consideration of the following amendments:

(*a*) I suggest that on page 3, section 3, the word "public" be inserted before health and wherever else that word is used in this bill.

(*b*) I suggest that you insert the word "average" before "user" wherever it appears in this bill. No manufacturer or distributor, or advertiser or publisher should be held liable for the exceptional reaction. The average user is the only fair test.

(*c*) I suggest that you strike out the words "or may be" in section 3, page 3, and wherever else it may occur in this same connection so that instead of reading as it now stands in this proposed bill (sec. 3, p. 3 (a) 1). "A food shall be deemed to be adulterated—if it is *or may be* dangerous to health," it would read "A food shall be deemed to be adulterated—if it is dangerous to public health."

Mr. Campbell stated to us yesterday that he could command a consensus of scientific opinion. So we would then have a definite means of finding out what "is" dangerous to public health without any "may be." This is a bill that once enacted will be a law for a long time. Mr. Campbell like the rest of us is only human. He may go out and meet with an accident. We have no promise from any one who might succeed him in an emergency on the point of referring scientific matters. Therefore let him and his colleagues get that consensus of opinion on medical questions properly lined up, make concrete provision for such scientific findings, and write this clearly and definitely in the bill. [Loud applause.] Please do not applaud, because you are taking my time and it is limited. It is your time as well as my time.

3. While I realize that responsibility for administration must be definitely and authoritatively vested—as a citizen interested in good government—I am opposed to the excess of power that this bill in its present form gives to one person. No matter how capable, how honest and sincere that one may be, if he could be personally responsible for even one tenth of the matters placed under his control and discretion herein accorded to him, he would have to be a superman. [Loud applause.] Please do not interrupt; let us go along.

Without any intent to let matters get out of his hands, this bill as it stands, would require a whole army of workers. Mr. Campbell, yesterday promised us that scientific questions would be referred to committee of experts or scientists fairly chosen. We believe he would keep his promise. However as I have already pointed out, like you and me he too is but human and some disability or accident might deprive the Department of his service and then where would we stand? If there is any idea or promise of having a committee of competent recognized medical experts, let's write that into the act. Without such definite provision what assurances would we have?

4. I would suggest that we take one additional step when it comes to "definitions and standards" left without limit to one man. While I realize that discretionary powers must be given every administrator to a certain extent, there should be a limitation to such powers in a democratic form of government. When it comes to definitions and standards I believe power should be limited and directed by a fixed commission or board whose membership would assure protection to the public. In this instance, I suggest the provision for the designation of a commission which shall be nonpartisan and which shall include in its personnel one medical authority, one pharmaceutical authority, one chemist, one lawyer, one business man, one technician in government administration, one consumer as the advisory committee to the administrator of this act. I might add that I would hope that at least one of these might be a well qualified woman.

5. Re voluntary inspection (sec. 22, p. 29.) I am frankly puzzled by the paradox of the apparently mandated inspection in section 13, page 17, and this voluntary inspection provision in section 22, page 29. This later provision is undoubtedly aimed to free the government of the expense of enforcement. As chairman of the New York Anti-Crime Crusade, I am fearful that it will lay this country open to further corruption. In the course of this hearing three suggestions have been made for providing financial means for enforcement of this so-called voluntary inspection.

(1) That the government should finance the enforcement—That would mean of course that the public finances it for the public, who are the taxpayers, are the government!

(2) Mr. Tugwell and Mr. Campbell advocate and have written into the act that the "manufacturers seeking voluntary inspection" pay for this inspection. That, too means the public will pay for it—for the consumer has long since learned that he pays for increased cost of production indirectly.

(3) A Mr. Phillip—I believe his name was—today suggested that the public pay for it directly. He did not designate how this was to be done no matter how you view it, as the boys today say "No matter how you slice it"—the public will pay for it. Now, I, as a consumer, am not unwilling to pay for my protection, but I do not believe that this section 22 will insure protection. Quite the contrary. It will take a whole army of inspectors to cover the whole forty or forty-five thousand plants that I have ascertained since my arrival here would fall under the inspection clause. If the inspectors paid by the manufacturers inviting them to inspect have the right to put the government stamp of approval on all productions without any check-up as section 22 provides, what is to hinder a corrupt inspector from O.K.ing an inferior or even harmful article if he were given a little bribe or graft to do so? It will open up just one more opportunity for graft and corruption. We have just lived through a 13-year period of wholesale graft and corruption growing out of a law that could not be enforced. We spent years of unrest and misery in bringing about its repeal. Are we going without caution and consideration to blindly repeat that mistake? If, as is easily conceivable after our recent experience, we are depending upon public protection which might so easily be violated by giving the power of setting the Government seal of approval into the hands of an army of inspectors, some of whom might be bribed with gifts or money to stamp such approval without conscientious investigation or examination—we may once again be deluding ourselves. Because of its dangers and because it is confusing in the light of Sec. 13 (a) page 17 which already provides for factory inspection I suggest that section 22 be eliminated in its entirety. (Applause.)

Please do not take my time. Then let section 13 which already deals with factory inspection include a definite check-up. You, yourself, Mr. Chairman, raised the question with Mr. Campbell as to the advisability of having the local health officers check up on the inspection. If such or similar provision were made the public would have better chance of protection. If the health officers in checking up find irregularities they report them—if they are remiss in their duties it is easy to fix responsibility.

I believe we need a stronger food and drug act that shall of course today include cosmetics, a recognized and very large industry in this country. I am not particularly concerned as to whether it shall be the old act adequately amended to insure public protection, or whether it shall be a new one embodying the good features of the old one and adding new reasonable and needed and effective ones. I should like to see law so carefully planned that it should be primarily remedial and punitive only where there is inherent intent of crime (unlike the queen in Alice in Wonderland, quoted by Mr. Thompson this afternoon, I do not approve of "bringing the verdict first and proving the guilt after). If and when the situation is remedial, I believe the act should provide for ready and quick action to protect the public. It is the public's protection in which we are interested and that I think should be our primary consideration. Whenever there is proof of intent to injure or defraud the public, I believe the Government should prove that intent or result by competent evidence and proceed accordingly. Most of all I hold it the responsibility of the thinking men and women in this country to inform themselves intelligently and clearly on pending legislation and make themselves articulate to their legislators so that neither in this act or any other one pending there may again slip any unsound provision that may take many years agitation to repeal if we find that it is not good or practical.

I am keen for a strong Federal Food and Drug and Cosmetic law, but one carefully considered so that it will not give encouragement once again to bootlegging in interstate traffic. While as Senator McNary this morning pointed out this bill is Federal and therefor interstate only, we women are concerned in any ill-advised provision that might slip in that would expose us to house-to-house salesmen bringing inferior and fraudulent and bootlegged wares to our homes within our own state limits.

I hope we shall get a new act with all the safeguards and protection embodied in this bill before us, but one so carefully considered and amended that it shall be clarified, definite, practical, reasonably enforceable and fairly enforced. One, as I said before, that will tend to foster respect for law and order in this country once again and not encourage further lawlessness.

I want a law with teeth in it—but with *real teeth* gripping hard and relentlessly into vulnerable spots threatening public safety and public health—not one with false teeth that may slip into unintended corners and nibble into honest healthy spots with results that might finally defeat some of its own purposes and obstruct the ultimate desired protection of the consumer by its possible abuses rather than its uses.

I am convinced by the frank and fair consideration which has been given every angle of the testimony offered here these two days, that this Senate Committee will after careful deliberation evolve just such a bill that will honestly serve the purposes of the Government, the public and the manufacturers all equally well and with equal fairness [Loud applause]. Thank you. May I say in passing that I am glad to see a woman on this Senatorial Committee whose decisions and recommendations will effect so many women who are users of drugs, cosmetics, and foods.

The CHAIRMAN. Thank you, we are always glad to hear from you, and I think that the many suggestions that you have made will be

of great value and assistance to the Committee in arriving at its findings in this matter. The next witness is Miss Alice L. Edwards of the American Home Economics Association.

STATEMENT OF MISS ALICE L. EDWARDS, EXECUTIVE SECRETARY OF THE AMERICAN HOME ECONOMICS ASSOCIATION

Miss EDWARDS. My name is Alice L. Edwards, Executive Secretary of the American Home Economics Association.

The American Home Economics Association is a professional organization of trained home economists, including approximately 9,000 members, with an organized association in each of the 48 States, the District of Columbia, Puerto Rico, and in Edmonton and Nova Scotia, Canada.

Through their study of household commodities home economists have become familiar with the provisions and administration of the present Food and Drugs Act. They know from experience that this act has been of untold value to consumers by protecting against impurities, adulteration, and false labeling; but they also realize that there are imperfections in the present law and that conditions have so changed since its enactment that the Government is unable to extend to consumers the protection originally intended.

The Association welcomes the opportunity to support the revision of the Food and Drugs Act and the extension of its functions to include the prevention of false advertising, to cover cosmetics, the control of drug products on the basis of therapeutic claims which are contrary to the general agreement of medical opinion, and the requirement of informative labels.

State laws alone will not suffice. A Federal or master law is required to prevent a hopeless lack of uniformity in regulations. Moreover, experience with the present act has proved that a Federal law will immeasurably strengthen State laws.

Home economists recognize the possibilities of advertising as a source of useful information about commodities and believe that truth in advertising called for by the proposed revision of the Food and Drugs Act would greatly increase public confidence in the claims made for worthy products. In our opinion, false or misleading statements in present-day advertising are rapidly destroying the faith of the public in all advertising, notably in the case of advertising by radio.

This has been the history in the case of false labeling. Twenty-seven years ago it was argued that the regulation of labels would wreck the business of the manufacturer, even of reputable products, whereas it has increased the confidence of the consumer in such products. Unfortunately truth in labeling has not been sufficient for the protection of the consumer. The unscrupulous dealer still resorts to advertising as a means of giving the public unjustified confidence in his products by statements in advertising which he may not now put on the label. As a result, we realize that if the consumer is to be protected from such false or misleading claims, the advertising as well as the labeling must be subject to regulation. We believe that truth in advertising would prove even more advantageous to honest business than has truth in labeling.

We believe that a law to regulate advertising is needed and agree with a statement appearing in the November 23, 1933, issue of Advertising and Selling which reads:

> Despite declarations of ethics, despite the establishment of regulatory boards, and despite the maintenance of high standards by individual publishers and advertisers, the fact that false, misleading, and harmful advertising still exists is undeniable. Abuses have not been controlled by intra-industry regulations.
>
> * * * These and other similar abuses cannot be definitely eradicated by regulations within the industry because (1) such regulations lack the united support of all members; (2) industry inertia defies effective action; and (3) the industry cannot impose penalties adequate to curb abuses.
>
> The declaration that the public must be protected is no idle slogan. That protection can be afforded only by a Federal law. The existing law has accomplished much but it falls far short of perfection.

Concern has been expressed by some that the provision in the bill which forbids labeling a drug as a cure for a disease when it is a palliative and not a specific cure would rob individuals of the privilege of self-medication. The answer to this is that the bill will not drive off the market legitimate products, truthfully labeled and advertised, and that to require them to be so labeled and advertised does not interfere with anyone's right to diagnose and treat himself; on the contrary it should make him feel safer in so doing.

Information as to the constituents in a commodity is essential if consumers are to profit from education and their experience in the use of a given commodity and to develop judgment in using them. We, therefore, heartily support the provision which requires the labeling of drugs as well as foods as to their ingredients.

May I, at this point, refer to the argument that is being used by canners and other food processors to omit grade labeling from the fair trade practices of marketing agreements or codes of their industries. They are urging that the use of such grade labeling "come about by due process of law", referring to the revision of the Food and Drugs Act now under consideration, however, a representative of the National Canners' Association at this hearing has asked that the proposed bill be so amended as to provide only for the labeling of substandard canned food.

The prices of canned foods are not reliable guides as to their quality. This is supported by numerous investigations by individual consumers in various parts of the country, including many by home economists; by the findings of the Federal Trade Commission; and by the judging tests carried on by canners themselves. The highest priced can is very frequently not the best, and the least expensive may prove to be a fancy grade. Therefore, we are forced to recognize that the consumer must seek some guide other than price as an indicator of quality.

One cannot be assured of obtaining a given quality by purchasing products from a certain State or locality. The quality of a nationally advertised brand may or may not be superior to that of nonnationally advertised goods. Furthermore the quality of a given brand does not always remain constant.

By a process of elimination through an examination of possible methods which might be used in determining quality, thoughtful consumers have come to believe that grade labeling of canned foods is essential if consumers are to be able to select these products intelligently.

Canners frequently comment on what seems to be the utter impossibility of developing clearly distinguishable grades of a sufficient number to inform the consumer of the shades of difference between various products. One can readily understand that a given canner wishes to gain the advantage of having his product put in the highest possible grade; but from the consumer's point of view fine shades of differentiation are neither desirable nor necessary, because their development would delay their use almost indefinitely and also because their enforcement would be very difficult and expensive. The use of four grades—A, B, C, and Substandard—would adequately serve the consumer's need. These would enable the housewife to select the truly superior product for those occasions and uses for which she wants an A grade; they would enable her to obtain a good medium grade for less exacting times and purposes, to select a C grade to use in certain dishes where the finer textures and flavors are masked, and to choose the substandard if rigid economy makes that necessary.

There is concrete evidence that it is possible to develop usable grades of canned foods. The grades for a considerable number of canned foods already promulgated by the Secretary of Agriculture and used in connection with the Warehousing Act are sufficiently satisfactory for the Government to use in connection with its own purchases of canned foods. Millions of dollars are loaned by the Reconstruction Finance Corporation and by bankers as well on foods graded by these standards. Furthermore, court decisions have proven these standards to be enforceable. If any of these grades are not well defined or prove unsatisfactory on more extensive use, they may and should be revised as seems desirable. The use of these grades in the retail sale of canned foods would certainly meet with the hearty approval of consumers and of home economists in particular the country over.

Brands and trade-marks would not become valueless if canned products were labeled according to their grades. The brands and trade-marks would continue to identify products put out by given concerns and would enable consumers to obtain products with the characteristics which tend to give distinction to each well-defined line of goods.

The women who crowd our grocery stores today are more anxious than formerly to learn the quality of the products they buy and to be saved from paying an A grade price for a grade C product. If they pay the grade A price, they want grade A goods. There is a real drive behind this desire because family funds are too limited to let them slip away without making every effort to get value received.

The December 1933 issue of Food Industries carries a letter written by Mr. F. M. Snook, field secretary of the Tri-State Packers Association, Easton, Md., which gives evidence that consumers are not alone in believing that canned foods should be labeled as to grade. Mr. Snook's letter reads as follows:

> To the Editor of FOOD INDUSTRIES:
>
> I want to congratulate you on the splendid outline of Senate Bill 1944 which you have in the November issue of FOOD INDUSTRIES. I am sure your readers will more fully understand what the thing is all about and just what changes the bill, if enacted, would make in the present food laws.
>
> I do, however, want to call your attention to your criticism of Sec. 7 (e)

The matter of standards and grades for canned foods and the statement of grades on labels, I realize, is one on which the industry has not yet reached an agreement. In saying this I am fully aware that the real objection to grading and grade labeling which is voiced by certain of the canning industry and some of the distributors is not founded on any belief that standards could not be made applicable for the entire country. On the contrary, back of it all, but kept, of course, in the background, is the fact that quite an embarrassing situatiou would arise if national advertisers were faced with the necessity of stating grades on labels.

The reference you make to a Federal definition of fancy canned peas is unfortunate, because, as a matter of fact, federal definitions and grades of canned foods have been ardently advocated and supported by Tri-State packers and opposed by certain Minnesota canners. I can assure you that Delaware and Maryland are perfectly willing to have their packs graded under the federal definitions, and we don't come out so bad after all.

The idea of different standards for different sections was exploded several years ago. I recall that some of the leading canners of a middle-western State fathered the idea. A definition for grades would necessarily differ, depending on the section of the country in which the commodity was packed. I recall distinctly that one canner went even further and advocated the idea that the definition would have to vary from year to year in the same locality, depending on the quality of the raw product as it came from the field. Of course, what he was trying to do was to grade the definition and not grade the product.

We have now reached that stage in the development of the canning industry in which we have set up Federal definitions for fancy, extra standard and standard products.

Then we check our products to coincide as closely as possible with these definitions. If a canner of peas in Delaware packs his peas at the proper stage of maturity and they meet the Federal definition of fancy, then they are fancy peas. If they fail to meet the definition and measure up only to extra standard, then they are extra standard. One of our Maryland canners this fall was awarded a contract for fancy Golden Bantam corn. This corn was fancy because it measured up to the Federal definition for fancy corn. Last year one of the Maryland packers of snap beans was awarded a contract for 10,000 cases of fancy snap beans in competition with New York and Wisconsin packers, because his pack of beans more fully measured up to the Federal definition for fancy beans than those submitted by canners of New York and Wisconsin.

I can assure you, L. V., that there will be no request by southern canners for a lowering of grade standards to fit our goods. On the other hand, we are fully aware that canned foods are not *per se* fancy because they happened to pe packed in a northern State.

One reason I welcome the opportunity to speak at this hearing is that I may voice the desire of consumers for the protection which they will have if this bill is enacted into law.

The statement has been made that there is no demand for this protection. I believe we need only to look into the method being employed by the opponents of this bill to understand why the public is confused about its value.

May I call your attention to the fact that certain of the opponents are doing everything in their power to muzzle the press and thereby prevent a correction of the misrepresentations of this bill which these opponents are using every means at their disposal to disseminate as widely as possible.

I am asking the privilege of having included in the record the 17 plans listed in the September 18, 1933, issue of the Drug Trade News, as the means Mr. Clinton Robb's organization, the United Manufacturers of Proprietary Medicines, is using to defeat this bill. They are as follows:

THE 17 PLANS

1. Increase the membership of association at once to present a united front in combating the measure.

2. Secure cooperation of newspapers in spreading favorable publicity, particularly papers now carrying advertising for members of the association.
3. Enlisting all manufacturers and wholesalers, including those allied to the trade, and inducing them to place the facts before their customers through salesmen, and in all other possible ways, to secure their cooperative aid.
4. Secure the pledge of manufacturers, wholesalers, advertising agencies and all other interested affiliates to address letters to Senators to secure their promise to vote against the measure.
5. Line up with other organizations, such as Drug Institute, Proprietary Association, National Association of Retail Druggists, and others, to make a mass attack on bill.
6. Appointment by the President of a committee to work in conjunction with Attorney Clinton Robb.
7. Cooperation of every member in forwarding to headquarters newspaper clippings and all available data as basis for bulletins and favorable publicity.
8. Cooperation of every member in doing missionary work in home districts to arouse public to the dangers of the legislation proposed.
9. Carrying to the public by every means available, radio, newspaper, mail, and personal contact, the alarming fact that if the bill is adopted, the public will be deprived of the right of self-diagnosis and self-medication, and would be compelled to secure a physician's prescription for many simple needs.
10. Arrange for conferences between Association Committee and representatives of all other trade associations interested.
11. Enlist the help of carton, tube, bottle, and box manufacturers.
12. Defeat use of ridicule by American Medical Association, proponents of the measure, by replying with ridicule.
13. Convince newspapers of justness of cause and educate public to same effect.
14. Setting up publicity department for dissemination of information.
15. Enlisting aid of Better Business Bureau in various cities.
16. Direct and constant contact with situation at Washington under leadership of Attorney Robb.
17. Pledge of 100 percent cooperation on part of every member of the association present for continued and unremitting activity in every possible direction to defeat measure.

One manufacturer of a patent medicine is carrying on his campaign against the bill by addressing newspaper publishers as follows:

You are about to lose a substantial amount of advertising revenue from food, cosmetic, and drug manufacturers.

Your pocketbook is about to be filched and you will see how if you will personally study, or have your lawyer study for you, the enclosed copy of the Tugwell bill and the two parallel analyses of it. The bill was introduced by two doctors in the Senate and House of Representatives respectively during the last session of Congress.

You publish your paper for profit and as a service to your community. In most virile business organizations the altruistic policies in the final analysis are means to the primary end which is profit. From a profit standpoint you will quickly see how you will be affected by this bill if it becomes law. From the standpoint of service to the people of your community we ask your careful reading of the enclosed folder entitled "The Economic Necessity and Moral Validity of the Prepared Medicine Business."

We ask you to take an active, aggressive stand against the bill, not as a matter of cooperation to us or other advertisers, but for your own business interests and the best interests of your community. An isolated editorial or two will not suffice in this matter.

1. You need to take an aggressive stand against this measure.
2. You need to bring all the personal pressure you can upon your Senators and Representatives.
3. You need to enlighten and thereby arouse your public against this bill that is calculated to greatly restrict personal rights.

If this bill should become law, we will be forced to cancel immediately every line of _____ advertising. It is our opinion that we would not endeavor to contend with the administration of the unreasonable sections of this bill and that the business would be "Milked" without any advertising or selling

efforts being put forth thereafter. We would be only one of the many drug, cosmetic, and food advertisers who would be forced to liquidate in this manner.

We hope you will act promptly and continuously on this between now and the time Congress convenes.

This letter provides concrete proof of the reason for the opposition of many publications to the bill now before this committee.

Mr. Chairman, the American Home Economics Association urges that S. 1944 be reported favorably to the Senate and that any changes your committee may see fit to make in the bill as it now stands shall not be such as to lessen its scope or to impair its effectiveness.

I thank you.

The next speaker will be Dr. Florence E. Wall.

STATEMENT OF DR. FLORENCE E. WALL

Dr. WALL. Mr. Chairman, and Members of the Senatorial Committee:

I would like to deal here, for a few moments, with some things which I think would be of interest in connection with cosmetics. Mrs. Sporborg forgot, I am sure, to include in the committee that she suggested for reference on matters of scientific interest, that that be covered also by a chemist. It was suggested that my reference would be to matters that are to be covered by a chemist. It is as a chemist that I appear before you this afternoon.

The CHAIRMAN. As you probably know, Dr. Wall is a fellow of the American Institute of Chemistry.

Dr. WALL. I regret that Mrs. Sporborg omitted to include a chemist in that list.

Mrs. SPORBORG. I thought I did. I do so now.

Dr. WALL. I am a consulting chemist of 20 years experience, and the last 9 years of my experience I have devoted exclusively to work in cosmetics. I find, and my personal analysis of this bill shows rather an unfortunate lack of knowledge of the cosmetic business which has now become almost exclusively a chemical industry. I have, since last May, tried to offer my constructive suggestions in the section that was to cover cosmetics as that would be included in this bill, but somehow connections were not made.

I can subscribe to many statements made by Dr. Reed because he is also a scientist and a professional man and he made the same criticisms that I do in regard to the clarity of definitions. It is said that a scientist can give you in 1 sentence what a lawyer will take 2 paragraphs for.

I desire to call attention to 1 or 2 sections. So much has been said that I might say that I will proceed directly to things that have not been touched upon. The term "cosmetic" which it says on page 2 includes all substances and preparations and so forth is too vague. I can give you an excellent definition of cosmetic which will include the therapeutic appliances which come in our work as it is now recognized in cosmetic therapy because this is also a field of research that has gone on despite its being ignored by many professional people. It has not been respectable for physicians to bother with cosmetics since about the year 1600. It is only really recently since manufacturers of cosmetic preparations, within the last 25 years, have been able to afford to find out what the business was really about.

The paragraph in the bill reflects that lack of knowledge. The progress that has been made in chemical research is truly astounding,

and the amount of research that has been done in cosmetics has not been exceeded by any other industry, except, perhaps, dyes.

First, my criticism of a chamber of horrors is that the worst thing in it is perhaps basic ignorance. They have taken these few things and brought them out as examples, completely ignoring about 95 percent of the business which has gone on and which is carried on in the most constructive way.

We have also been telling the public in lectures and writing, that the most harmful thing is not what we put in the cosmetics, but what these manufacturers say about them. I think the worst thing any cosmetic does that is done largely through a lack of information. Some of the manufacturers do not have the information that they should have, and that has been responsible for many of these conditions which have arisen. Processes can be controlled, and when they can be controlled, it is indeed simple to take care of the situation. I have already told Dr. Copeland I am willing to offer definite suggestions in connection with the paragraph in the bill. This definition of drug is kind of silly to me. It says that a drug is any appliance—that is ridiculous, because that would include a pair of scissors that the barber uses to cut your hair with. This is just a silly aside, but this is a matter of adulteration, which we consider as a chemist.

I am discussing now the average drug in connection with the matter of adulteration. It seems that the inherited opinion of what an adulterant is something which is added to a substance which is going to spoil it, but you can have adulterants, and dangerous ones, that are not mutually exclusive. For instance, potassium cyanide does not have to be adulterated to kill you. It can be the most pure potassium cyanide there ever was, and it will kill you just the same. In other words, you can have dangerous things which are not adulterated, and you can have adulterated things that are dangerous also. They do not have to be mutual. The definition of an adulterant, if it is taken to be something to be added to another compound, it will vary with the nature of that compound; for instance, water, which has been added in many creams, is considered to be an adulterant if it is present in more than 25 percent quantity. There is a lack of definition of adulterant which is going to be a pitfall.

One of the worst clauses that we object to is section 10, page 14, tolerances for poisons and poisonous ingredients. I have read that clause all through and if I could add two words "or cosmetics" I would say that you were really getting at what this is supposed to get at, spray residue and insecticides and things that are in or on a surface of some sort, but to keep cosmetics in that definition is to invite a most perplexing condition.

There are any number of cosmetics that may be used safely on the surface of the skin, and properly so, but if they are taken internally they may be, in many circumstances, harmful. We know that many substances can be used externally with great benefit, but if taken into the body even in small quantities, they are likely to become dangerous. For instance, if you get mascara on the eyes, that is on the eyeball, it will cause a severe smarting, and I would not care to swallow any of it.

This reminds me of an old story which was told by a doctor when he had prepared some drugs for a man to take, and he wanted to prescribe a dosage for it, so he told him to take as much as he could hold on a dime—because it was a rather strong medicine—and the

next day when he called on this man he saw that he was in a rather serious condition and he asked him if he took the medicine to the quantity that would be able to stay on a dime and the man said that he had no dime so he used two nickels. This illustrates very clearly what happens when otherwise innocent drugs are used improperly. We are not looking for scarecrow nor for corkscrew interpretations. We want them to be straight and definite. Under the definition as we have it now, if you sell something, anything to be used externally, if it is taken internally, or if it goes in your eye, the person who makes that can be liable for injury if this provision were incorporated in the law.

I should like to see the words "or cosmetics" taken out. I think that is what it really means, spray residue and insecticide.

I should like to suggest also taking over the adulteration of cosmetics and I refer now to page 6, section 5. Dr. Beal objected to that when he was brought forward, and I shall be very glad to offer a concrete suggestion in that regard.

The CHAIRMAN. You are offering some language for that?

Dr. WALL. Yes; I can offer you language for a definition, and I can clear this up so it will not be so vague.

The CHAIRMAN. I will be glad to have you do so.

Dr. WALL. This section 5 has to do with the adulteration of cosmetics. We will pass everything that has to do with material medical because that has changed so frequently since 20 years ago, when we started the chemical research, and if I may coin the term "material cosmetica" has changed just about as frequently.

Years ago everything was in connection with plant substances and then metallic substances, and then 20 years ago the metallic substances in drugs have been replaced by modern chemical synthetics and very little is known about them. The one thing that must be covered is the question of personal idiosyncrasy. It is unsound to exclude a whole group of substances because a few individuals might be susceptible, and the matter of determining tolerances can only be determined after a long and severe undertaking for years and years. I hope it will be done, and when done, properly.

Misbranding: We have goods taken care of and we have drugs taken care of, but we have no misbranding of cosmetic accounted for. That has been omitted. The industry is one which justifies the protection against misbranding, which is frequently possible in our industry. It deserves the protection against misbranding certainly as much as the other two industries. I have listened with great interest to all the discussion of the publication of formulas. You owe it to the legitimate manufacturer to protect him. The man who has pirated that has simply taken the hard work of another manufacturer and gained all the benefit of it. This, of course, brings in a class of people who are not professional—the amount of pirating that is done is something appalling—and they feel that all one must do is to simply analyze a substance and duplicate it, that is not the point. The control of food and drugs bring in, largely, manufacturers of some size, but the control of cosmetics brings in every little beauty-shop operator who if she or he wants to pay $5 for an analysis can become a manufacturer. Every person who manufactures cosmetics should be protected. The big houses who have spent so much time and money on research work

every year should be protected. I would like to suggest, and I can also suggest some words for that.

The CHAIRMAN. We will be glad to have that.

Dr. WALL. In summing up I would like to say that I feel it is to be regretted that there is so much hysteria about cosmetics. I lay that largely to the dread mystery in which it has been shrouded so long. The physicians dropped it and it was taken up by very improper people for a long time. It was not until the chemists took it up that it became respectable again.

In September I had the privilege of serving as chairman of a committee working in connection with the New York Health Department to get up a display of the Chamber of Horrors in connection with cosmetics. The first release that went out—but first let me go back and give you the history of that:

The idea was to fit in right along with the Food and Drugs Act and the Health Department was commissioned to collect up a display that would show to the public all of the harmful and dreadful things, things against which they should be warned. I went away for 10 days and Dr. Barker had been commissioned to collect these dreadful things. I came back and called him on the phone and when I called him and asked him what had been done he said, "We cannot find enough to make a decent show." I said, "That is fine." When the releases came out, they had evidently already gone to press and it had been written by some representative who evidently had written it up in the future tense, and it stated that this display was a display of all the harmful things that could be used by the public. As a matter fact, the display that was there was a splendid exhibit of the raw materials that the various creams were made out of and it told why the value of the cream bases helped in some measure to account for the prices of the product. That was entirely good propaganda. At another corner there was a display by the department where I gave a lecture on hair dyes. My objection to similar things that appear here are purely esthetic. I have never known of anybody being killed by hair dye, but some of it is certainly not very flattering, although the better grades are. I was on the committee that helped to revise the sanitary code of the city of New York; I was invited merely as a chemist to sit in on the meetings of the committee as a whole, in connection with the protection of the public. I decided that if people are still in business who have been in business for the last 75 years, it cannot be so deadly—the product which they manufacture—but if they have products which contain certain things they should be stated. They should put informative labels on them so the public can decide whether they want to buy that particular thing and use that particular thing or not.

As the ideal solution of this I would like to suggest that our present law, as it stands, be extended to cover the advertising; that, we need to improve, to bring in corrections that are most urgently needed at the moment. The cosmetic industry has had some trade-practice conferences, and perhaps can take care of its own troubles. That was their idea, but the N.R.A. came along, and I think they are going to function under that. The ideal thing would be to have foods and insecticides where they belong, under the Secretary of Agriculture, and I think the Secretary would have troubles enough with them. I would like some time, it cannot happen day after tomorrow, but I would like to see drugs and cosmetics taken out of the administration

by the Department of Agriculture, and it should be treated as a new administration of drugs and cosmetics in which we shall include all therapeutic appliances, drugs and cosmetics in the new National Institute of Health where they would be subject to the Surgeon General, and with an advisory board consisting of physicians and pharmacists and chemists who can be assumed to know something about these questions and would be specilaists in this line. They would know about things that pertain to our business, and they will not be determined by people who have their troubles already with food and insecticide.

I suggest the establishment of an advisory board to serve as a grievance committee to protect against unwise publicity before facts are ascertained. But, publicity and prosecution should follow any complaint or finding toward them.

Re: Publication of formulas: I also want registration of formulas with a competent bureau—I suggest the advisory board—so that questions of advertising claims can be settled before copy goes out and publications could also apply to such a bureau to see if advertisement is acceptable and truthful in substance. This will work towards higher standards because if advertisement is refused and refusal is based on actual knowledge itself it may prompt manufacturers to improve products and bring them up to standards that will be acceptable.

A list of "harmful or deleterious substances" should be carefully defined to include—

A. Substances forbidden at all times. These would be very few.
B. Partially harmful substances that are allowable up to defined percentages.
C. Substances specifically for external use, generally harmless.
D. Substances generally harmless, that can affect predisposed persons—and this protection should apply to labels as well as all accompanying literature.

It is not suggested that these lists are to be included in the law. They should be for the information of the bureau, available at request. Lists can be made for food, drugs, and cosmetics, impartially, and I can supply much valuable information on these categories.

But, I still say that these medical, drug, and cosmetic matters belong more properly to some other administrative body than the Food and Drug Administration of the Department of Agriculture.

Section 9 (e) at the foot of page 13 should be revised. The wording is amusing in its implication. An advertisement is false in one magazine but not false if it is in a medical magazine. If you mean that curative properties can be stated more explicitly to the medical profession, say it in some other way. After all, the medicos need to keep up with the new things just as well (even more) than the laity.

Contemporary medical opinion. This is especially important on cosmetics because so few physicians know about them at all and practically all the medical literature is against them based on trouble-cases only; hence, exaggerated. They are learning that their newer ideas are worth more.

The CHAIRMAN. We appreciate the remarks by Dr. Wall, and we think they will be of value in the consideration of this bill. We will call on Mr. Arthur Kallet, Secretary of the Consumers Research Incorporated, Washington, N.J.

STATEMENT OF ARTHUR KALLET, SECRETARY CONSUMERS RESEARCH, INC.

Mr. KALLET. My name is Arthur Kallet, and I am Secretary and one of the representatives of Consumers' Research, a nonprofit organization with 50,000 ultimate consumer subscribers, and interested solely in the protection of the ultimate consumer, and supported solely by ultimate consumers.

We had prepared a detailed analysis of the proposed bill from the consumers' point of view, but we shall not present that analysis.

With respect to the bill, I wish merely to say that while we believe the bill far too weak to give the consumers the adequate protection to which he has every right, it is nevertheless infinitely superior to the present act, and if a stronger law cannot be obtained, this at least should be passed.

We do, however, wish to place a brief statement on record which we feel is an unpleasant but unavoidable necessity if this legislation is to receive proper consideration from the present moment until it passes the Congress.

Before reading the statement, I wish to point out that it is now a few hours within the close of the hearings, and no ultimate consumer has yet been heard. Nor has even a modicum of consideration been given to his interests by the speakers or by the formal or informal expressions of the Committee, yet it is or should be evident to everyone that except as this bill serves, aids, and safeguards ultimate consumers, these deliberations have no meaning of value, except a few pitiful remarks.

It is difficult at best for consumers to obtain a fair and full hearing before a congressional committee dealing with legislation which would dislodge strong vested interests of manufacturers of cosmetics, quack medicines, and adulterated and misrepresented foods and drugs of every sort. The preponderance of commercial interests present and speaking at great length for the protection of their profits makes it absolutely essential that the fairest possible dealing with every ultimate consumer interest should be assured. As representatives of the consumer we do not believe it possible to receive such fair dealing, not only in the hearings but also in the committee's deliberations, when the chairman of the Committee is, we are informed, receiving pay for broadcasts on behalf of a nationally advertised product the claims for which will be adversely affected as being untrue and misleading under the terms of the pending legislation. These broadcasts, on behalf of Fleishman's Yeast, were started after the introduction of the pending bill. The Senator's fourth broadcast in the series took place last night, following the close of the first day's hearings.

The CHAIRMAN. Have you observed any unfairness on my part?

Mr. KALLET. Yes. I have. I should want to discuss that with you after I close this statement.

The CHAIRMAN. By all means proceed.

Mr. KALLET. During the course of that company's broadcast statements were made which were gross exaggerations and which find no support among reputable American physicians. Because reputable American physicians are not permitted by their code of

ethics to testify directly or indirectly on medical nostrums, Fleishman's have been found to buy their testimony abroad. Much of this purchased testimony has been repudiated by the medical faculty at Vienna.

In view of this commercial activity for a concern which will be affected by the pending legislation, we protest on behalf of the consumers for whose protection this bill was drawn, and we request that the hearings be reconvened under a new committee and an unquestionably impartial chairman.

This statement is made by the secretary and is signed by myself and Mr. Schlink.

To answer Dr. Copeland's statement, we do not find that very hard, because I merely listened to those that came forward to press their claims by taking up what otherwise would have been time for the consumers, and the two have banded together in the considered effort to prevent the ultimate consumer from being heard. I have sat here and listened to those that have come forward all day yesterday and today up until 2 hours ago and no consumer had been heard.

One of the representatives of the ultimate consumer, I noticed, received a great amount of applause from the commercial interests represented here.

If the consumer is to receive adequate protection, we believe that a more aggressive spirit must be displayed in seeing that the clause is properly described, and that his necessities are properly placed before the Committee, for, after all, this is an appeal designed to protect the public, to protect the ultimate consumer, and not to protect the commercial interests concerned, as one might gather from listening to the two days of testimony.

The CHAIRMAN. We are very much obliged, Mr. Kallet. (Applause).

The CHAIRMAN. The next speaker is Dr. Schlink, of the Consumers' Research.

STATEMENT OF DR. F. J. SCHLINK ON BEHALF OF THE CONSUMERS' RESEARCH

Dr. SCHLINK. Mr. Chairman, ladies and gentlemen:

Like Mr. Kallett, I spent many days in preparation for these hearings, in an earnest attempt to represent, so far as they could be represented, the interests of 50,000 ultimate consumers.

We really speak for those ultimate consumers, and we know that we speak for them.

Hundreds of them have written to members of the Senate and the House and to President Roosevelt himself, in support of this bill, and we have copies of the letters which many of them have sent.

Through our work 50,000 consumers, at least, know that they have a stake in this bill, and we propose to tell them, as often as may be necessary, that that stake is not being protected under the system which is set up for hearings of this type.

I am not going to make a speech.

I am going to close very briefly by saying that I reenforce the statements of Mr. Kallett. We prepared those statements together. We have made them with a clear consideration of our responsibility.

We recognize that we have to know what we are saying. We think it exceedingly important for 125,000,000 people in America that proceedings of this character should be carried on under auspices which are so unmistakably impartial that there can be no question raised about it either now or hereafter.

In order that the ultimate consumer should receive the safeguards he has every right to be afforded under this bill, the members of this committee or subcommittee which handles the hearing must represent, neither indirectly or directly, neither inferentially nor by their conduct of their discussion, any interest whatsoever save that of the general public.

I recognize that it is an unprecedented thing for a representative of the general public to speak in this way. I recognize that he usually held, properly, perhaps, in the light of the very clever men of law and of science who speak here, very properly regarded as the victims of the operation of commercial machinery.

I think the time may have come, gentlemen and ladies, when that process may no longer be safely carried on.

Thank you very much.

The CHAIRMAN. We are very much obliged to you, Dr. Schlink. Dr. Schlink spoke at my invitation, as he had not sent in his name.

The next speaker is Mrs. C. I. Hendrickson, of Washington, of the District of Columbia Home Economics Association.

STATEMENT OF MRS. G. I. HENDRICKSON, DISTRICT OF COLUMBIA HOME ECONOMICS ASSOCIATION

Mrs. HENDRICKSON. Senator Copeland and members of the Committee, opponents and proponents, I am Gladys Irene Hendrickson, a home maker, representing the District of Columbia Home Economics Association, which is a member group of the American Home Economics Association.

It, like the national association, is composed of elementary and secondary school, college, and university teachers of home economics, dietitians, nurses, members of scientific and journalistic staffs within the District and Federal Governments, and in industrial and business organizations throughout the District of Columbia, together with a large group of home makers.

This association most heartily endorses Senate bill 1944 as an instrument of protection for consumers in their purchases.

We are endorsing the bill in its entirety, Mr. Chairman, not because we believe it to be a perfect instrument, but rather that we regard it as a starting point for the regulation of a situation which we now feel is absolutely hopeless, and we hope from the extremes of the opposition and the support that we may expect a reasonable mean.

It is the belief of our association that the provisions of the bill regarding advertising are mutually helpful to all concerned, producers, distributors, and consumers alike. In "distributors" we include advertisers.

Since the provisions of the bill preclude the possibility of misleading statements in advertising, consumers' confidence in the products advertised and the descriptive material used should be immeasurably strengthened.

Since reduction of waste through member purchasing is one of the major objectives of the association, it believes straightforward nonambiguous advertising can be most helpful in realizing this objective.

Every consumer desires adequate protection against harmful ingredients in all articles for both internal and external use and therefore welcomes the extension of prerogative and function given the Food and Drug Administration in the provisions of the bill regarding drugs and cosmetics.

It is most reassuring to us to have our Government arranging its legislation to meet the constant changes in manner and practices of living such as are to be found in the provisions of the bill regarding mechanical therapeutic devices, as it gives us cause to believe that the unscrupulous may not expect to exploit the public at the expense of its health.

As in the instance of the reduction of economic waste, and as a means toward that end, the establishment of definite standards in all products purchased for household and personal use has long been a major objective of the association, especially in the home makers' group.

We are, therefore, desirous that this portion of the bill, together with the provisions regarding labeling, be made as extensive as possible in its scope.

The CHAIRMAN. Pardon me; you would not favor any change particularly in those items of the bill?

Mrs. HENDRICKSON. No, I do not, Mr. Chairman.

The CHAIRMAN. Thank you.

Mrs. HENDRICKSON. Since in the understanding of the members of the association the bill as written offers so much protection to honest ethical producers and distributors, and also offers such excellent opportunities for the practice of fair business methods, this group feels such business organizations have much to gain and little to lose under its enactment.

The District of Columbia Home Economics Association wishes, therefore, to go on record as endorsing all the provisions of S. Bill 1944 as protective of the best interests of its members and needful to the well-being of all as consumers.

It urges that the committee recommend the speedy enactment of the bill into law.

Mr. Chairman, may I at this time read the concensus of opinion of a group which met at my home yesterday and discussed the bill. I had not requested the time for that.

The CHAIRMAN. Certainly.

Mrs. HENDRICKSON. In addition, I wish to express the opinions of 40 women meeting informally to discuss this bill, and, while some of these may seem very curt, very abrupt, and even rude to some of you advertisers, nevertheless I shall offer them:

That in the opinion of this group to which I refer, any manufacturer who refuses to subject his products to the scrutiny of the bill is thereby automatically admitting some inferior or harmful quality in that product, and that, therefore, we, as consumers, can have no confidence in any sales appeal regarding it;

That no action proposed by the Government with the protection of public health as its objective could be considered too drastic or too costly;

That we can have no confidence nor understand the motive of a manufacturer or advertiser who is willing to abide by the letter of the existing law regarding labeling, and insists upon creating other impressions through other forms of advertising;

That we urge the formulation of legislation which will give the consumer—Dr. Campbell particularly—the greatest sense of protection against the unscrupulous, unprincipled manufacturer.

I take issue there with the man who spoke this afternoon on the small percentage of those people. It is always the small percentage against whom we have to protect ourselves, because, by and large, we all like to believe we are fairly decent people.

I want to second the statement of Mr. Thomas Elliott that at any social or economic cost which may ensue as a result of the effect upon the unscrupulous, that cost is infinitesimal beside the continuance of the present practices of the people who would be involved in that situation.

Finally, in closing, Mr. Chairman, I cannot resist asking Mr. Parlin of the Curtis Publishing Co. how he reconciles his vehement attack upon the rating of products which all we home makers have welcomed, with the wide-spread campaign of the Dole pineapple people to educate the public at large to use their second- and third-grade products.

Thank you.

Mrs. Hendrickson later secured permission to insert the following documents at this point in the record:

THE MONEY-CHANGERS IN THE TEMPLE—AN ANALYSIS OF THE GOODWIN PLAN

[By Robert C. Dexter, in the Christian Leader, Dec. 16, 1933]

Many of our churches have inquired of officers of the American Unitarian Association regarding the so-called Goodwin plan. It has, therefore, been thought advisable by the administrative council to request the secretary of the Department of Social Relations to prepare a statement outlining the plan. Further than that, it has been considered desirable that this statement shall also include pertinent comments and criticisms on the plan for consideration by our churches. It should be borne in mind that Unitarian churches are congregational in polity and that any statement only represents the opinion of its author. Some of our churches, in common with many others, have already committed themselves to the support of the plan as outlined.

In this connection it is interesting to note that at the last meeting of the General Alliance Board on November 10 the matter of endorsing money-raising schemes was discussed. The alliance board felt that this was not its function and the following vote was passed:

Voted: That the executive board feels that the alliance is organized to stress the religious and spiritual side of our churches, and that it does not endorse the exploitation of the branches by business organizations.

While the officers of the association take essentially the same position as that taken in the alliance resolution just quoted, they feel that they are bound at least to present their point of view to our churches for their consideration.

THE PLAN

The Goodwin plan was conceived by Adolph O. Goodwin, a business and advertising executive of Chicago, Ill. It is worked in the following manner: The Goodwin Corporation is approaching all churches in the United States, both Protestant and Catholic, generally making its contact through the women's organizations, although this is not always the case. It asks that each organization appoint at least 10 representatives, whom it calls broadcasters. These broadcasters are instructed to approach the purchasers in the church, particularly the women, and ask them to sign an agreement to purchase a certain brand of nationally advertised products. The products cover practically every con-

ceivable field "from chewing gum to automobiles", to quote the Goodwin plan prospectus. There is, however, to be only one brand or make in each field. The individual products have not as yet been selected, but the selection will be made in the near future, probably by January 1. The individual purchaser also agrees to keep certain evidences of her purchase, labels or coupons, which she is to turn in to the broadcaster once a month, and the broadcasters in turn in each church pool their evidences and send them in to the main office of the Goodwin Corporation. The Goodwin Corporation then turns in the evidences to the manufacturer, who returns to the Goodwin Corporation 3½ percent of the retail sales price, and the Goodwin Corporation sends 2 percent of the retail sales price to the broadcasters for the use of their church or church society.

In announcing the plan the Goodwin Corporation claims that it will select only goods of "a high quality." It, therefore, must of necessity stand back of the type of goods selected. It also states that the plan is "definitely dedicated to upholding the principles of social justice for working men and women, as advocated by all church denominations." These principles of social justice as stated in the prospectus are the following:

1. The maintenance of a living wage to working men and women.
2. Reasonable working hours.
3. Reasonable working conditions.
4. A willingness to work toward a permanent maintenance of employment.

The Goodwin Corporation, therefore, not only gaurantees the one brand which it endorses to be of high quality but it also guarantees that the firms manufacturing this product shall abide by the principles as stated.

RECEPTION OF THE PLAN

The plan has received highest endorsements from leaders in the religious and social field, among them being some of our own people. It must be especially gratifying to the promoters of the plan to find the names of such men as Father John A. Ryan and Father James Fogarty of the Catholic University and the University of Notre Dame among the endorsers. Literally thousands of church organizations have already "signed up" with the Goodwin Plan and are awaiting the publication of the selected list. The latest information which we have from the Boston area is that 126 churches of various denominations in Greater Boston are cooperating in the plan, among them two Unitarian churches, and the response in other parts of the country has been equally great.

On the other hand, there have been church leaders who have been critical of the plan. Especially outstanding has been the criticism of the plan in The Christian Century, which has published two articles, one by Georgianna Merrill Root in the issue of November 8 under the title "Are Church Women Being Exploited?" and the second an editorial entitled "The Goodwin Plan" in the issue of November 22. The Christian Century criticizes the commercialization of religion in an editorial, as well as the monopolistic aspects of the plan. It contends that despite its apparent success the plan will not be permanently successful, as the churches for 30 years have been gradually "developing a conscience on methods of raising church money."

The Christian Century's faith in the churches of the country is gratifying, but one cannot but be somewhat doubtful in view of the large number of churches which have promised to adopt the plan.

WHY THE CHURCHES YIELD

The reasons for which the churches have taken up the plan are various. In the first place, there is the financial inducement. There is no question that if the plan succeeds there is a huge financial reward to the churches and incidentally to the Goodwin Corporation. The Goodwin Corporation prospectus indicates this by stating that 10 broadcasters in an average church with 10 families apiece and each family spending a minimum of only $5 per week on goods shown in the Goodwin catalog, would mean a $520 income for the church, for 20 broadcasters it would be $1,040 and for 50 $5,200 a year. The present financial burdens which many churches are carrying make it quite understandable that this amount of money is a tremendous inducement.

A second reason, and a much more laudable one than merely financial need, is the ethical standard promulgated in the plan. On the surface it seems to present a way by which the churches can make their social ideals effective. To quote an advertisement of the Goodwin Plan in The Christian Century written by Dr. Walter Macpherson, of Joliet, Ill., "The social-justice program is the only practical means * * * whereby the Christian women of America can make effective their instinctive abhorrence of their silent partnership in the profit wrung from the masses by exploitation."

That there is something appealing in this aspect of the Goodwin Plan there is no doubt.

CRITICISMS OF THE PLAN

The various criticisms of the Goodwin Plan have been foreshadowed in what has already been said. First of all, there is the general criticism, clearly brought out in The Christian Century editorial, that it is a commercializing of the churches. It is perfectly true, as advocates of the plan may well claim, that this is nothing new. The church fair or the solicing of adverisements and donations from local merchants is also a commercialization of the church. The difference is in degree rather than in kind. This is a wholesale commercialization. It definitely and specifically ties up the church and church people to certain manufacturers to the exclusion of their competitors. That there are practical difficulties of this kind, the advocates of the plan themselves admit. They agree, for example, that any church or any individual may cross off from their catalog list certain goods in which they desire to have another choice than that listed. This is to prevent the difficulty that might arise, for example, if one of the leading members of the church were the dealer in Chevrolets and the Ford happened to be the car that was chosen by the Goodwin Corporation. But even so there is no question but that the plan will be criticized from this point of view. The church, after all, is a specially privileged institution; it is free from taxation. The reason for these special privileges is that the church is assumed to be rendering a broad community service. If the church in place of rendering this broad community service to all becomes a center for propaganda of certain articles to the exclusion of others, it may well be contended that it is betraying its trust. While the temple may not become a den of thieves, it will certainly be considered to be usurping the place of the market. The manufacturers whose goods are not placed on the preferential list will not hesitate to criticize organized religion if in any large number of churches continue to support this plan, and such criticism will be exceedingly difficult to meet. The 2 percent commission in this case might well be compared to the mess of pottage for which the church has surrendered its sublime inheritance.

The second criticism which can be leveled at the plan has to do with the claim that the goods selected are of high quality. A careful reading of the Goodwin plan literature fails to disclose any method by which this quality is to be tested. It is true that the Goodwin plan reserves the right to change the brand selected if the quality falls off. Anyone who has studied the difficulties with which an impartial organization such as the Consumers' Research has met in trying to determine quality of goods, or anyone at all conversant with the careful studies made by the Government Bureau of Standards in Washington, knows that a determination of the quality of goods is no slight task.

The essence of the Goodwin plan is that the goods selected shall be nationally advertised, and it may well be that the highest quality goods are not nationally advertised. The temptation, too, for the Goodwin plan promoters will be to select goods which have the widest public sale, and that does not necessarily mean they are of the highest quality. The Goodwin plan does not anywhere claim that the goods selected will be the very best, and in using the term "high quality", its promoters undoubtedly escape any legal criticism, but, practically speaking the only way by which quality can be determined is by careful, continuous, scientific research, and there is no indication so far that the Goodwin Corporation has made careful provision for such objective study of the quality of the goods selected.

A third criticism, and one which should appeal most of all the the churches, is that regarding the ethical standards under which the goods selected are to be manufactured. This qualification for inclusion in the Goodwin catalog is one which its churchly defenders fall back on. It is, therefore, worth examination. Originally the qualifications were those outlined above:

1. The maintenance of a living wage to working men and women.
2. Reasonable working hours.
3. Reasonable working conditions.
4. A willingness to work toward a permanent maintenance of employment.

These very general statements The Christian Century calls "nothing but sentimental selling talk." Impelled by such criticism, the Goodwin Corporation has recently issued a bulletin clarifying its position. The basic wage which the

Goodwin Corporation presumably maintains as reasonable is that outlined in the new N.R.A. Code. In such a position there is nothing in advance of what the Government is doing and which all manufacturers are pledged to adopt. But in a new bulletin the Goodwin Gorporation takes a short step in advance and promises that it will not recommend any manufacturer who does not agree that "a predetermined part of increased profits shall be awarded to employees as increased compensation." Five pages of the new bulletin are given over to an outline of this plan, but nowhere is it specifically stated what percentage is to be given to the employees or just how the ruling is to be enforced, except that the Goodwin Corporation reserves the right to examine the books of the corporation.

Reasonable working hours are defined as those which "will afford sufficient leisure for spiritual, educational, and cultural opportunities; to conform, in time of emergency, to those hours established by the Federal Government, but in no case to exceed an 8-hour day and a 6-day week." Since the Federal Government's present standard of reasonable working hours is much lower than an 8-hour day and a 6-day week, it would seem as though the schedule of hours as suggested by the Goodwin Corporation in times other than emergency is a step backward rather than forward.

Decent working conditions are defined as those which "relate to sanitation, light and ventilation, safety devices, protection against occupational diseases, injuries, and morality." These are high-sounding phrases, but in reality they mean little or nothing. Insofar as they have any meaning, in most States they are provided for by legislation. In the same connection, the Goodwin plan requires that its manufacturers shall abstain from employing child labor. It sets the limit for child labor as 16, but allows exceptions between 14 and 16 for a 3-hour per day employment between 7 a.m. and 7 p.m. Here, again, there is no advance over what is required under the N.R.A. and what it is hoped will be permanent Federal enactment when the child-labor amendment becomes law.

And, finally, the Goodwin plan manufacturers are pledged to "work toward security and permanency of employment", which is defined as "agreeing to work toward the attainment and security and continuity of employment for workers." Of course, any employer would pledge to work toward security, but it is noticeable that no practical method toward this end is suggested. There is no indication of any special stabilization scheme or unemployment insurance or anything else which might be of practical importance.

And then as a means toward enforcing even these minimum standards, the Goodwin plan makes the following proposition:

We propose to set up a social-justice committee composed of one representative of each of Protestant, Catholic, and Jewish denomination from within our own organization, whose duty it shall be to see that the principles of social justice enunciated herein are understood, and accorded with in principle, by those manufacturers before we offer them the sales-stimulating service of the Goodwin plan, and to investigate and to endeavor to adjust any charges of violation of these principles in any such manufacturing establishment * * * and in the event of failing to so adjust the matter, it shall be referred to an arbitration board of 3 to be selected, 1 by the Goodwin Corporation, 1 by the manufacturers, and the third by these 2; and our own committee shall consider the decision of this arbitration board to be final in all matters pertaining to the alleged violation of these principles; and in the event that a manufacturer refuses or fails to correct and adjust such offense within a period of 6 months, the Goodwin Corporation may cancel its contract with said manufacturer in accordance with provisions to this effect, which shall be incorporated in the contract with said manufacturer or manufacturers.

It will be noted that the committee called to pass on the application of principles is to be made up of men from within the organization and not of outside disinterested experts. It is doubtful if any group of outside disinterested experts of standing would attempt to enforce such a loosely drawn code as that outlined above, but, in any event, if the public is to have confidence in them they must be from without rather than from within the organization.

The Goodwin Plan promoters should be given credit, however, for adumbrating a policy which if more carefully thought out and freed from commercialization might well provide a means by which organized religion might impose its ethical standards on industry. The Consumers' League with its "white list" has made beginnings in this direction. If the churches of America, with the assistance of recognized experts in the field of economics and social relations, were to make a careful study of the industries of the country and propose a "white list" of their own with no commissions attached, they might make a very real contribution to

social justice. The 2 percent vitiates the plan and subjects it to severest criticism, and on top of the 2 percent there is the percentage paid to the promoters which would quite naturally bring in the question of commercial bias.

CONCLUSION

In view of the above facts, what should be the attitude of the churches when approached by the sales agent of the Goodwin plan? There is but one answer to this question. The Goodwin plan is a commercilization of religion; it presents very important practical difficulties in administration; it gives to its promoters, if successful, an almost monopolistic control of a very large market; it may well force out of business and into bankruptcy many manufacturers whose goods are of at least as good quality and produced under at least as good conditions as those selected. (This is especially true of the smaller manufacturer with a small budget for national advertising.) So far at least it presents no practical method of objectively selecting goods of "high quality," and, finally, its social-ethics provisions for industry are very general and in many respects not above those already incorporated in our various N.R.A. codes, and there is no effective objective method of judging the observance even of these very general standards. In a congregational system of church government, it is obvious that individual churches and individual societies within the churches will accept or reject the Goodwin plan as they see fit. We are here simply suggesting some of the considerations which should be borne in mind before we allow the money-changers completely to control the temple.

We protest the Goodwin plan to be distinctly antisocial both in its inception and operation.

It appears to be antisocial in its inception and the exposition of it by the representatives of the firm, in that according to the spoken statement of its representative appearing before the Ladies' Aid of Universalist Memorial Church on Tuesday, December 10, 1933, it presents as its individual program requirements for improved working conditions among the employees in the plants of the manufacturers subscribing to the plan, which are already a part of the body of factory inspection laws of many States and definitely so of the N.R.A. Codes. By so doing it is an example of the use of misleading statement so frequently employed by advertisers to create favorable receptions and impressions for the products being advertised.

It presents also that widely disseminated statement which is as apt to be untrue as true; namely, that the fact of Nation-wide advertisement is a guarantee of superior quality.

It would be as distinctly antisocial in its operation as in its inception in that it deliberately proposes and intends to maintain in the cost of the manufactured commodities it advertises 3 percent of the consumers purchase price from which the consumer can get no returns since the Goodwin plan adds nothing to the quality of the product nor in any way facilitates its distribution.

At the time of the present crisis in our national life when the extremely low point of consumer purchasing power is a matter of such great concern we condemn any plan which takes 3 percent of that purchasing power and gives nothing for it in return.

We therefore propose that those interested in this plan of raising funds for the support of their churches make a record of the cost of such products as appear on these lists and return to their churches 2 percent of that total thereby eliminating their gratuitous presentation of 1 percent of that amount to the Goodwin Advertising Co.

As a local matter the plan is distinctly anti-social in that any increase in the consumption of nationally advertised products automatically works against the local producer able to supply his market with products of equal quality at the same price.

Clara Wilson; Mrs. Frederic W. Perkins (wife of Dr. F. W. Perkins, pastor of Universalist National Memorial Church); Julia R. van Schaick (wife of John Van Schaick, Jr., editor of the Christian Leader); Donna P. Bonner; Eleanor Bonner, (pastor's assistant Universalist National Memorial Church); Mrs. L. C. Ricker.

VOICE OF THE PEOPLE

Expressions from readers upon topics of current or general interest are welcomed. Writing should be on one side of the paper only and should not exceed 300 words. Anonymous communications will not be printed and letters unaccompanied by self-addressed, stamped envelope will not be returned. The News reserves the right to shorten letters of excessive length.

THE TUGWELL BILL

[Birmingham News, November 16, 1933]

To the Editor the News:

The Age-Herald last Saturday and The News Sunday printed editorials that were patently anticonsumer and proadvertiser. I refer, of course, to the column-long articles on the Tugwell bill, which seems to be so offensive to your papers. Inasmuch as the newspapers exert a powerful influence on the thought and policies of this country, I feel that some reply should be made to your unwarranted criticism. I also feel that the general public for whose benefit this law has been proposed, should understand your motives in printing these "editorials."

In your issue of Monday, November 13, you have 19 remedies advertised in your paper, most of which would be controlled, if not banned, by the Tugwell act.

As to the merits or lack of merits of the articles, I will refrain at this time from expressing an opinion.

It is an established fact that such products are almost uniformly conventional mixtures of well-known chemicals having practically no effective action on the diseases for which they are sold. Most of the chemicals have been known for decades, and even the formulas of many of the mixtures are not new, as often claimed to be. Even the name "patent" is misleading. The manufacturer, to get a patent on his remedy, would have to give away the secret of its composition, and he regards it as an invasion of his private rights when legislators, as a few have done, suggest that disclosing patent medicine formulas on the label would be in the public interest.

Mr. Editor, you must realize that such a bill as this would be a boon to long-suffering John Consumer. If this bill fails, your children and my children will pay the bill in bad health from poisoned foods, adulterated and impotent drugs, and poisonous and fraudulently advertised patent medicines and cosmetics. I urge you not to miss this one chance to make your influence felt in the right direction. Inspect this proposed bill, item by item, and by all means publish such items as are objectionable, but do not forget your readers' interest entirely by a blanket indictment of the whole measure as you have done so far. Forget the money and revenue angle for the moment, and I am sure we will see eye to eye.

After all, the greatest good that will come from the passage of this bill will be the elimination of blatant cure-all remedies from the air. With such passage, you can again turn on your radio without being constantly besieged with names and claims of fake nostrums. You will agree, Mr. Editor, that this alone would warrant the enactment of this measure into law.

J. STUART STONE, JR.

Birmingham.

WHAT IS TIMELY?

[Survey Midmonthly, December 1933]

"Untimely" is the reiterated refrain of the protests which drug and cosmetic manufacturers are pouring into the mails in opposition to S. 1944, the so-called "Tugwell bill" to extend and strengthen the Federal Food and Drug Act. (See Survey Midmonthly, October 1933, p. 383: Radio and Rouge.) In the midst of discourses on constitutionality and "the right and duty of self-medication" these plaints murmur repeatedly that business is in no position to stand revision. The same adjective, this time as "an untimely announcement", bobs up in a quoted statement by the New York Association of Private Hospitals, deploring the report by the Academy of Medicine on maternal deaths, to which reference is made elsewhere in these pages. Hearings on S. 1944 are scheduled to start December 7 before the Senate Subcommittee on Commerce. Consumers—which means all of us—will be well advised to obtain a copy of the bill itself from the Federal Food and Drug Administration and watch the papers and our Senators during a lively fight. In the process one may ponder the philosophy of timeliness. We have the old adage that it is never too late to mend. But is it ever too early, when, as the Department of Agriculture has shown, Americans are misled into spending millions of dollars for products that are inadequate or useless for their advertised purposes and sometimes poisonous, even deadly; or when, in the considered opinion of the Academy of Medicine, women are dying needlessly? Untimely for whom?

LYDIA PINKHAM AND OTHER WASHINGTONIANS

[By Paul Y. Anderson in The Nation]

WASHINGTON, *December 9.*

The youthful ardor and rash idealism of the Brain Trust finally have contrived to make Washington the scene of a mortal conflict over a fundamental issue of human rights. No doubt it was fated from the beginning to be so, although few could have suspected fate of choosing such a vehicle. The latter is now discovered to be the so-called Copeland, or Tugwell, bill, which seeks to enlarge the scope of the old pure food and drugs act. Without bandying words it can be stated that this measure frankly challenges the sacred right of a freeborn American to advertise and sell horse liniment as a remedy for tuberculosis—or, to phrase it in a wholly different way, his God-given right to advertise and sell extract of horsetail weed as a cure for diabetes. Breathes there a man with soul so dead as to decline this gage? Maybe so, but his like is not to be found in the ranks of the lobby which has rallied here at the behest of the patent-medicine manufacturers, the wholesale druggists, the proprietary association, the retail chains, and the newspapers, periodicals, and radio broadcasters which thrive on their patronage. Here we find them, one and all prepared to die for good old Lydia Pinkham, cascarets, listerine, and the other and less celebrated benefactors of suffering humanity. Nothing than can be done in such a glorious cause has been left undone. Newspapers and periodicals have been informed in emphatic language that advertising revenues are at stake, and have been reminded—just in case they forgot—that "we all exist to make profits." Broadcasting companies are alive to the danger, and opponents of the measure have not omitted to retain a Democratic national committeeman or two where it might be expected to do the most good. The battle already is fairly launched, but it will not attain its full fury until Congressmen begin to hear in earnest from the country newspapers, the religious periodicals, the corner druggists, and the particular nostrum manufacturers who have been in the habit of contributing to their respective campaign funds. This is precisely the sort of constitutional question which stirs men to the very depths of their pocketbooks.

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Although the actual preparation of the measure was intrusted to Assistant Secretary of Agriculture Tugwell, it embodies the ideas of the permanent officials of the Food and Drug Administration, gleaned from the experiences of 27 years in trying to enforce the letter and spirit of the old law. Under this old law the manufacturer or processor of food and drugs is responsible for the claims which appear on the labels of his product but not for his advertising. Accordingly, it came to the notice of the department experts that although the label on a bottle might content itself with the modest statement, "Recommended as a vegetable tonic in conditions for which this preparation is adapted", it was publicly and triumphantly advertised as a remedy for almost every malaise known to women. The manufacturer who suddenly transformed an old horse liniment into a new tuberculosis remedy was equally diffident on his labels and equally expansive in his advertising. He paid a woman to write testimonials for his product until she died of the disease, and then paid her son to continue them over her name—priding himself, I suppose, on having invented a novel form of ghost writing. Concerning the diabetes "medicine" extracted from horsetail weed—which commonly grows along railroad tracks—the department collected several testimonials which it now exhibits appended to the death certificates of those who wrote them. There was also the celebrated case of the Pittsburgh millionaire who drank an advertised "radium water" until the bones of his skull disintegrated, and that of the pretty Ohio school teacher who beautified her lashed with a drug store cosmetic which promptly ate her eyeballs from their sockets. There is not space to list the legion of searing depilatories, arsenic-laden hair tonics, deleterious toothpastes, worthless mouth washes, and the like. The proposed bill would simply compel the makers of these preparations to tell the truth about them. This, the makers contend, would impair or destroy their business, thus violating their constitutional rights. Somehow, I doubt whether this argument would convince the girl who lost her eyes, even if it were read to her.

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The CHAIRMAN. Thank you, very much.

The next speaker is Mrs. F. C. Dugan, who is director of the State Bureau of Food and Drugs of Kentucky.

STATEMENT OF MRS. SARAH VANCE DUGAN, DIRECTOR BUREAU OF FOOD AND DRUGS, STATE BOARD OF HEALTH OF THE STATE OF KENTUCKY

Mrs. DUGAN. My name is Sarah Vance Dugan, director of the Bureau of Foods and Drugs of the State Board of Health of Kentucky, and I am here today representing the State Board of Health of Kentucky and representing the consumers of Kentucky, since the State Board does represent the consumers.

As the State official charged by the State Board of Health with the administration of the State food and drug laws in Kentucky, I am greatly interested in the passage of S. 1944, "a bill to prevent the manufacture, shipment, and sale of adulterated or misbranded foods, drugs, and cosmetics, and to regulate traffic therein; to prevent the false advertisement of foods, drugs, and cosmetics, and for other purposes", since the State of Kentucky is largely a rural State and therefore primarily a consuming State for manufactured foods, drugs, and cosmetics, rather than a salesman State offering manufactured products to other consumers.

This bill, S. 1944, is a consumers' protective measure and as such Kentucky officials and Kentucky citizens are interested in it.

I feel that the Federal Department of Agriculture, represented by the Food and Drug Administration, has ably represented the consumer in the formulation of this bill, and I do not feel that we as consumers and I as representing the State of Kentucky, a consumer State, need worry about the protection given in that bill.

I have been thoroughly familiar for the last 14 years with the enforcement of the State food and drug laws and have, of course, been brought in contact with the enforcement of the Federal Food and Drug law as it affected conditions in our State, and I know full well how the Federal officials have been handicapped by the conditions as they exist in the present law.

Many of the other State food officials have felt the same way that I have.

In fact, at meetings that have occurred in the past few months, since the introduction of this bill, of State officials, they have unanimously adopted resolutions approving S. 1944 in particulars.

For instance, the meeting of the Ohio Valley Conference of Food, Drug, and Health Officials in Cincinnati in October, which had representatives from States and cities in Indiana, Kentucky, and Ohio, adopted a quite lengthy resolution, which I will not read at this time, but which I will ask permission to file in the record.

The CHAIRMAN. It will be included in the record.

(The resolution referred to by Mrs. Dugan will be found following her remarks.)

Mrs. DUGAN. The State Officials of the United States, meeting as a group in Milwaukee in September, also adopted a resolution approving this bill in its entirety.

The Association of International Milk Inspectors adopted at Indianapolis a resolution approving this bill.

I am the president of the South-Central States Association of Food, Feed, Drug, and Health Officials, which has representatives of 7 of the central-southern States. We have not had a meeting since the introduction of this bill in Congress, but I have word from nearly

every one of the members of this association approving the bill and asking me to present their statements to the Committee, and I will ask permission here not to read them but to file them with the record.

The CHAIRMAN. They will be filed.

(The statements referred to by Mrs. Dugan will be found following her remarks.)

Mrs. DUGAN. I also have statements from 18 other State health officials and State food officials representing departments of agriculture and State boards of health, both of whom have in various States the authority to enforce State food and drug laws.

Each of these statements, in turn, endorses this bill and hopes for its passage as written.

I also have a statement from the chairman of the Public Welfare and chairman of the Public Health of the Kentucky Federation of Women's Clubs, endorsing the bill, and particularly approving that section of the bill which provides for publicity of all action as it occurs within the Department, as it affects food, drugs, and cosmetics.

I have a further resolution adopted by the Women's Auxiliary of the Kentucky State Medical Association in annual session in September, approving the bill, and the resolution as adopted by the American Public Health Association has been mentioned.

I want to call attention also and file with this committee a statement as printed in the bulletin of the State board of health covering the bill, and a statement which appeared as an editorial in the Herald-Post of Louisville, "Why We Need a Pure Food and Drug Law," written by Mrs. Heller, president of the Kentucky Federation of Women's Clubs, endorsing the bill.

I further would like to file a statement published by the State board of health of Florida on the new Federal Food and Drugs Act, endorsing the bill.

I call your attention to these resolutions and ask again permission to file the statements and resolutions.

The CHAIRMAN. They will be printed in the record.

(The statements and resolutions referred to by Mrs. Dugan will be found following her remarks.)

Mrs. DUGAN. Simply because the statement has been made before this committee that the passage of this bill would so endanger State food and drug laws that it would be impossible for manufacturers to operate for 10 or 12 years with any system, I might bring to the attention of this committee the fact that at the present time the State food and drug laws do not exactly follow the Federal law.

As an actual fact, my own State law does not follow the Federal law. It is stronger; and very nearly as strong, as regards drugs and the labeling of drugs and the advertising of drugs, as the new bill.

The reason that we have not been so successful in enforcing that law in Kentucky is that most advertising mediums are in interstate commerce and most of our foods and drugs and cosmetics are sold in Kentucky as subject to the Federal Food and Drug Act, and our courts, as most State courts are, and local courts, are loath to go beyond the powers given in the Federal law, because of the fact that they do not care to endanger home industries.

If we would take action against a local industry under that law, we would be unable, I am sure, due to the way that the law is written,

to take any action at the present time in the State of Kentucky under our own law until a law equally as strong should be passed by the Federal Congress.

The question was also raised about small-town newspapers and the fact that they are, of course, interested in the publication and the sale of advertising space.

I have a statement here copied from a letter which was sent to a small-town newspaper in my State by a proprietary remedy manufacturer in which the following statement is made:

> You publish your paper for profit and as a service to your community. Most rural business organizations, the altruistic policies, in the final analysis, are a means to the primary end, which is profit.

They further make this statement:

> If this bill should become law we will be forced to cancel immediately every line of our advertising.

I make the contention that if this particular product would be forced to cancel every single line of its present advertising, that it appear that since they fear that that would be necessary, should the bill become a law, for them to cancel all of their advertising, that they are pretty sure that their present advertising is, to say the least, misleading, if not directly false and untrue. [Applause.]

In closing, I simply want to quote what our State board of health has published in its bulletin just off the press:

> There is no valid reason anywhere, why the proposed legislation should not become law; there are many and compelling reasons why it should. It is necessary for the proper protection alike of the consumer and of the honest manufacturer and dealer—the former, in his health and his economic welfare; the latter, against unfair and dishonest competition.

May I ask the privilege of filing this statement, which gives more in detail our reasons for supporting the bill in its entirety, as well as any certain, specific item?

Thank you very much.

(The statement of Mrs. Sarah Vance Dugan referred to above is as follows:)

As the State official charged by the State board of health with the administration of the State food and drug laws in Kentucky, I am greatly interested in the passage of S. 1944, "a bill to prevent the manufacture, shipment, and sale of adulterated or misbranded foods, drugs, and cosmetics, and for other purposes," since the State of Kentucky is largely a rural State and therefore primarily a consuming State for manufactured foods, drugs, and cosmetics, rather than a salesman State offering manufactured products to other consumers.

This bill, S. 1944, is a consumer's protective measure and as such Kentucky officials and Kentucky citizens are interested in it.

The duties of the State Board of Health of Kentucky are to protect the citizens of the State from all agencies and products which may prove dangerous to the health of the public.

Limitations of the present Federal Food and Drug Act have prevented the fullest exercise of this protection to our people.

State laws patterned after Federal laws can only go in their enforcement so far as the similar Federal law is interpreted by the courts.

State courts hestitate in their interpretation of the provisions of a State law to place restrictions on manufacturers within their State when manufacturers in a bordering State can ship in interstate commerce a product of no greater value and similarly apparently violating at the source of manufacture the State law.

Our State laws cannot reach into another State for sanitary supervision of a canning factory, for instance, and yet that possibly insanitary factory is not only in competition with a local factory so far as methods and practices are concerned, but the present Federal law is powerless to prevent the manufacture of food products even under the most insanitary and repulsive conditions unless the can or bottle of food which is finally sold in the neighboring State shows unmistakable chemical, bacteriological, biological, or organileptic evidence of putrefaction, adulteration, or dangerous uncleanliness.

Those of you who know of the care taken in your homes in the preparation of the food served on your tables do not care to contemplate the filthiness, uncouthness, and inexcusable dirtiness of some of the places where food is handled for human consumption and prepared for transportation in interstate commerce.

I do not want to intimate that all or even a majority of food establishments belong to the class mentioned.

Happily, in the food industry, we have a majority of manufacturers who are striving to prepare and market such foods as they can be proud to offer for sale to the public.

Today, under the provisions of the present Federal food and drug law, a man can go into the food business in a horse stable, haul his product hundreds of miles by truck and offer his merchandise for sale in another State. State officials in the place of sale are powerless to investigate the source of such supply, and until there are deaths or illness caused by such food, which, only by the grace of God, is prevented in most cases, no agency, Federal or State, can protect the unsuspecting consumer.

The provisions of S. 1944, under section 12 and 13, give to public-health officials the first hopes of adequate protection from a sanitary and health standpoint of foods shipped in interstate commerce.

One of the most powerful protective legal weapons granted to State health officials has been the power to quarantine suspected dangerous food products to prevent their sale during the sometimes necessarily long period of laboratory investigation to prove presence of adulterated products inimical to the public health.

The present Federal food law has required proof of adulteration or misbranding before the legal steps are provided for removal of a dangerous product from the market and many are the instances that a truly dangerous product has been sold and consumed because Federal officials charged with the enforcement of the Federal food and drug laws do not have the same power of public-health protection now given by most State laws to the food and health officials of the smallest town or county.

As a representative of the State Board of Health of Kentucky, I urge the passage of S. 1944, with no changes in section 16, that will in any way impair this authority of quarantine or seizure.

Under section 7, paragraph (f) of the bill, S. 1944, the very wise provision is made for the labeling of food for which no definition of identity has been established. No requirement is made for publication of the formula of proprietary foods, but the common name of ingredients of any such food must appear on the label. Under such a provision, worthless products cannot be sold as miraculous health-giving secret preparations. Drugs cannot lap over into the food provision to escape the requirements of drug laws. There was recently offered for sale in Kentucky by mail to nonmedical practitioners a series of so-called "Food Cubes" labeled with a fancy name and identified one from the other by a number and a different color dye for the pills. The fanciful name inferred but did not state that the products were made of alfalfa and vegetable products. Analysis of two of these products showed that they were composed of potent drugs of various types masqueraded as a food.

Authorities state that from 20 to 30 percent of the population is subject to some type of allergic reaction, such as hay fever, asthma, eczema, and hives due to consitiveness to some component of food or some individual drug. From our own personal knowledge even this figure seems to be conservative. We are, each of us, familiar with numerous cases within our own family and circle of friends, of individuals who have most unpleasant reactions from such simple foods as milk, eggs, wheat, or corn. Labels on compound or proprietary foods, plainly stating the common name of the ingredients, will go far to prevent allergic illnesses of this considerable proportion of our population.

Section 11 of the proposed bill, S. 1944, wisely provides for the fixing of definitions and legal standards of foods. In individual States law enforcement officials and boards now have the power to promulgate standards for food products offered for sale within that State. Such standards have no effect when a product is to be sold in a neighboring State and at the present time the State officials in the place of sale of such products are handicapped by the plea of lack of Federal food standards, even though their State may have standards. State

food officials welcome the plan for Federal food standards and have individually and by groups endorsed this bill.

The provisions of section 17, of S. 1944, have become increasingly important. Nation-wide chains of food and drug sales establishments can and do consider the seizure of small shipments of their products as minor tribute paid for illegal, profitable business, the meager fines of the present law as necessary license for chiseling the public.

In Kentucky recently a butter manufacturer paid in State court a nominal fine for sale of short-weight butter. This company and many others do a big interstate business and they have regularly paid yearly or oftener two and three hundred dollar fines for the interstate shipment of underweight butter. An estimate was made of the profit possible at the one plant on a continued underweight sales policy, $16,000 a year would represent the "overrun" made by this plant if they continued the sale of underweight butter for 1 year as was indicated in records. Penalties should be such as to discourage violation rather than to permit payment for violation.

The present law has done much to protect the pocketbook as well as the health of the public in its 27 years of existence, but we do not have to go far to find numerous examples of cheats and frauds in a percentage of the products offered for sale as foods, drugs, and cosmetics.

As State food official, I am constantly brought to face with the problems of, in some cases, honest, ignorant individuals who are anxious to make a little money and who feel that they have something to sell in the way of a drug or a food mixture on which they can make easily 50 to 100 percent profit if only they can put the product on the market. We have the classical example of approximately a cent's worth of a common laxative salt selling for 150 times its value because of a neat package and blatant advertising.

Another product is somewhat more modest and a mixture of 15 cents worth of laxative herbs is sold for $1.50 as an absolute cure for obesity.

The statement of Dr. W. W. Martin, of Harlan, Ky., president of the Kentucky State Medical Association of "Willful Ignorance" describes this type of charlatan and money grabber. Dr. Martin says in his presidential address before the medical association in September 1933:

"The most vital of all the arts is the art of living. Therefore, it is the most difficult to learn and the most exacting to practice. But a relatively few people have succeeded in mastering even the elementary principles involved in the accomplishment of this most enviable achievement. Those who have approached the ideal preserve an elusive modesty or a positive timidity in acknowledging such a rare and difficult accomplishment.

"To make the task of dealing with this subject as simple as possible, we will try the experiment of reducing it to mathematical principles and assume that it has three dimensions—length, breadth, and depth. The first of these—length—is most pertinent to the medical profession and to the individual."

"Tersely stated, longevity may be acquired in at least, two ways. (1) By scientific resistance against the invasion of the forces that are detrimental to vital processes. (2) The complete eradication of the agencies of destruction before they can even enter or approach the sacred precincts of our bodily tissues. Sounds simple, like putting salt on a bird's tail. May we enumerate some of the factors that abbreviate our existence. I would place at the head of the list as captain of the men of death, willful ignorance. I would write it in capital letters, italicized and underscored for emphasis. By the term, I would not imply the sense in which it is generally used. I do not mean by ignorance a lack of culture or education or the social refinements that obtain in polite circles. Nor do I use the term as it is so often sneeringly applied to classes and geographical boundaries, the inhabitants of remote and obsecure districts. But, I mean that which is indicated by an attitude of indifference toward acquiring knowledge that is essential to individual welfare and failure to cooperate with the efforts and agencies that are put in force by the Government for the preservation of health and the extension of life.

"The kind of ignorance we are discussing may be divided into two classes: Willful and excusable. The former perhaps includes the larger group. As an example we consider the multitudes that scoff the laws of public hygiene, not only condemn but defy vaccination and the antitoxins and disown the dangers of contagion, hold in derision the germ idea, and mock the medical profession. There are many otherwise educated and intelligent people who might be termed 'biological skeptic' who hold as naught all physiological phenomena that affect the human body while accepting and believing parallel phenomena in the lower orders of life. This class is so stubborn, so inconsistent, they refuse to look at or consider the evidence for fear they be convinced and stand in their own sight guilty of error."

Whoever heard of any of these predatory insects proposing a plan for prevention of illness either singly or collectively?

Nobody begrudges them the money they filch from their unwary victims or the patronage they command or the worship they receive. Their real infamy exists in the fact that they stand between the hopes of their followers and their chance to live. These people, having no regard for the dangers of contagion or the fears of infection, become the means of transmission and the source of wide and mortal epidemics. If those opposed to the established principles of physiology, pathology, and hygiene could be kept within their own ranks, no one would care to interfere seriously with their programs. No one would be seriously concerned with their mortality statistics. But it is the helpless infant and the innocent bystanders that are demanding protection, and we are morally responsible for its deliverance. This constitutes the most delicate and difficult responsibility the medical profession has to bear, because people instinctively resent any interference (apparent or real) that seems to restrain them in the exercise of what they consider to be their rights and privileges, even though the proposed restrictions are obviously for their benefit and protection. On the other side, their prophets are continually preaching the doctrine of the sanctity of personal liberty to stimulate their resistance and at the same time blatantly accuse the regular profession of the sins of envy, jealousy, and selfishness. A situation like this is one of our major problems and must be adequately dealt with if we discharge the duties of our high calling. To be so it will require an artful exercise of all the patience, diplomacy, skill, and strategy that can be acquired. But the reward is correspondingly great. I am sure that if we were relieved of the serious obstacles constituted by quacks and charlatans, we would increase expectancy to 100 years.

Codes and marketing agreements are making provisions for profits and percentage of retail sales prices over manufacturing costs or wholesale prices on many of our basic food commodities and in most of our great essential industries, but nowhere have I noted a plan for curtailing or limiting the enormous profits now existing in a great branch of our proprietary remedy manufacturing industry. The examples cited above are only a few among many that have come to my attention in the past few months, any food and drug official in any State in the Union could cite many more. The Notices of Judgment as published by the United States Department of Agriculture would prove a fertile field for thousands of examples.

A rather ridiculous example appeared in Louisville recently. A 10-cent store had a white-coated demonstrator treating the feet of a pretty girl with a truly magic foot powder. According to the spiel of the demonstrator, this powder would cure all the ills feet are heir to. An analysis indicated that the 25-cent box contained about 7 ounces of soap powder with sodium silicate. I would guess that the profit was only about 500 percent.

It would seem that provisions of S. 1944 would go far to provide a code to prevent undue profits to manufacturers of worthless nostrums by requiring a statement of the active drug ingredients, as well as the amounts. Even the most ignorant purchaser of patent medicine who can read would know that he was being cheated when he paid $12 a pint for a water extract of the wee horsetail as the exhibits of the United States Department of Agriculture depicted at the Century of Progress.

Many of our "patent" medicines depend on laxative or purgative qualities for their effectiveness and advertise as "stomach, kidney, and bowel remedies." If even a portion of the public could be informed that such products are laxative in nature, some of the 18,000 deaths each year from appendicitis might be prevented. Authorities state that 11,000 of these deaths are traced to the administration of purgatives.

It is utterly impossible to even estimate the cost to the public of falsely advertised and worthless drug products. I mean the cost in lives, as well as in money.

Public welfare workers and county health nurses tell me that in visiting homes of families who are on the relief rolls, unable financially to purchase adequate food and clothing, they will find a bottle (price $1 and up) of some well-known nostrum purchased with money that should go to buy very necessary food.

The present Food and Drug Law has hampered the Federal officials in accomplishing the design of that law to protect the public from misbranded and adulterated foods and drugs.

We would not fight a war with the antiquated weapons of 1906, we would not care to make a journey in a 1906-model automobile, and few of us would care to keep house with 1906 facilities. We have been expecting 1933 Federal officials to adequately protect from adulterated and false food and drugs a 1933 population assailed by true and false advertising printed and spoken word, with a 1906 law, framed at a time before radio, talkies and printed advertising had reached the peak now attained.

For 14 years, I have been closely associated with the enforcement of the State food and drug laws, and I am well aware as you are that even with constant reminders, the public buy drug products and cosmetics in particular more from their advertised claims than from any statements made on their labels.

To determine the effectiveness of the present law in all its inadequacy, I ask you only to compare the labels of some well-known "patent" medicine with its radio or magazine advertising.

The other night a radio speaker stated plainly that a certain soap "would grow new skin" on the user's face. Such fabrication is really ridiculous, and almost laughable if it were not for the deep tragedies similar statements cause.

I want to quote again from Dr. Martin's very interesting paper, The Art of Living, where he touches on just advertisement as it covers a single class of drug products:

"Ever since Lister published his discoveries concerning antiseptics, their effects and mode of action have been distorted in the public mind by the cupidity of commercial interests. Unscrupulous advertisement has misled the public and caused them to attribute powers of both cure and prevention to substances containing antiseptics that cannot be realized. In that way people are led to assume unwarranted risk and exposure expecting antiseptics to provide protection. It must be thoroughly understood that a germ must be brought into direct contact with antiseptic agents before it can in any way affect them. It must be remembered too, that germs are also endowed with the divine faculties of self-preservation. They do not come out in open places and invite themselves to slaughter. On the contrary, they hide in the obscure and hidden recesses of the body that are invisible even to the microscopic eye. They fortify themselves in fortresses of fatty tissues that is inpenetratable to aqueous solutions, thereby rendering some of our noblest efforts at antiseptics futile. This situation can best be illustrated by the example of a farmer spraying his barn to exterminate the rats. All aqueous solutions of antiseptics are of either doubtful value or have none whatever. Killing germs in vitro (test tube) and in vivo (body tissue) are two vastly different problems. Any reliance upon antiseptics without due consideration of ways and means of establishing the necessary contact is doomed to failure and may lead to fatal consequences. After all, there is only one antiseptic in which complete reliance can be found and that is heat. A temperature of 160° F., or more. Next to that, the factor of safety deserving the greatest degree of confidence in the basic rules of cleanliness typified in soap and water and vigorous application."

The present Federal Food and Drug Law, does not in any way cover cosmeti cs and that vast army of users of such products are made victims of their own harmless and pleasant vanity coupled with unscrupulousness of a minority of manufacturers of this class of products. The consumer at present is helpless, there is no source of information available for their guidance and I can vouch for their avid interest since I have come in direct contact in a number of States with women's organizations. The women are the users of cosmetics and as the representative of that great branch of consumers, I can only urge that Congress through the enactment of S.1944, afford some protection to our health, our looks, and our pocket books.

In the present law, the definition of drugs does not include a vast army of mechanical, electrical, and statis devices advertised for sale as treatments of all types of conditions and diseases from double chins to diabetes.

Only last year an enterprising concern with offices in all the large cities of the country was selling and may still be selling an electric belt. One sat within its circumference and could, in accordance with their literature and newspaper and radio advertisement be successfully treated for "Asthma" through "Varicose Veins", and alphabetical list of 27 diseases. This utterly valueless apparatus sold for $67.50 cash or $75 on time. At the present time there is no law preventing the sale of such trash. Only the depression has had any effect on the sales.

Another simple electric heater, such as is sold for heating the shaving water or the baby's bottle, was offered for sale as an electrifier of water which would give such magical properties to a glass of water so heated, that a hopeless invalid for 30 years could be cured of a bone deformity. Such frauds and chiselers of our

money and hopes will be prevented from operation by the enactment of this bill, S. 1944.

State food and drug laws in many instances are patterned after the present Federal law. The proposed bill makes little change in the basic principles as they affect foods except to strengthen the Federal law, and in fact bring it more in line with the provisions of many State laws.

There are few States actively engaged in the enforcement of the drug portions of their State laws, due mainly to lack of appropriations as well as to the fact that the great majority of packaged drug products are sold in interstate commerce and as such is subject to the Federal law. Many times it has been brought forcibly to my attention that our State laws are only so strong in enforcement as our Federal Laws are interpreted, regardless of the fact that our State laws are in many instances stronger and more forceful in language. State courts are very apt to balk at interpretations contrary to decisions under a somewhat similar Federal law, and few States have the funds to build up a case to be fought through the final courts. The strengthening and broadening of the Federal law as it applies to the drugs and advertising will go far to clear the markets of all States of fraudulent products and the passage of this bill, S. 1944 will be hailed by State health and food officials as evidenced by quoted expressions of opinion from such officials, attached to this statement.

The Association of Food, Drug, and Dairy Officials of the United States adopted a resolution approving the proposed bill in September of this year at their annual meeting in Milwaukee.

The Association of Food and Health Officials of the Ohio Valley passed a resolution approving the bill in detail and urging its passage at their quarterly meeting in October 1933.

The individual members of the South Central States Association of Food, Feed, Drug, and Health Officials have authorized me as their president, to submit their statements urging favorable action by this committee and the need for passage of this bill.

Health officials, State food commissioners, and State agricultural departments have added their approval of the bill and are urging its passage.

The State Board of Health of Kentucky, in its monthly bulletin, makes this final statement in an article discussing the proposed act, S. 1944.

"There is no valid reason anywhere why the proposed legislation should not become law; there are many and compelling reasons why it should. It is necessary for the proper protection alike of the consumer and of the honest manufacturer and dealer—the former, in his health and his economic welfare; the latter, against unfair and dishonest competition."

RESOLUTIONS ADOPTED BY THE OHIO VALLEY CONFERENCE OF FOOD, DRUG AND HEALTH OFFICIALS, AT ITS REGULAR QUARTERLY MEETING HELD OCTOBER 25, 1933, AT CINCINNATI, OHIO

Whereas, by direction of the President of the United States the Department of Agriculture has prepared a bill, designed to supplant the present food and drugs act, which has been introduced in the Senate as Senate bill 1944; and

Whereas, nearly 27 years enforcement of the Federal food and drugs act revealed many deficiencies in its provisions through wich serious abuses of the public health and the consumer's purse arise; and

Whereas, the United States Department of Agriculture, with the approval of the President of the United States, has prepared a bill which was introduced in Congress by Senator Copeland as Senate bill 1944, designed to correct these abuses by strengthening and extending the present law in the following particulars:

(1) Prevention of false advertising of foods, drugs and cosmetics;
(2) Prevention of traffic in poisonous cosmetics;
(3) Establishment of safe tolerances for added poisons in food;
(4) Establishment of legally binding definitions and standards for foods;
(5) Power to require permits for manufacture of potentially dangerous products when public health cannot otherwise be safeguarded;
(6) Prevention of curative claims for drugs when such claims are contrary to the general agreement of medical opinion;
(7) Requirement for definitely informative labels for food and drugs; and
(8) Power to protect the public health from future products and practices which may prove dangerous.

Whereas, the Ohio Valley Conference of Food, Drug, and Health Officials has consistently endorsed legislation to protect public welfare through safeguarding the purity and truthful representation of food and drugs, therefore, be it

Resolved, That the Ohio Valley Conference of Food, Drug, and Health Officials endorse Senate bill 1944 and that every effort be made to secure the enactment of this bill during the forthcoming session of Congress.

Statement Covering Senate Bill 1944 as Published by the State Board of Health of Kentucky in the Bulletin of the State Board of Health of Kentucky, December 1933, Volume 6, No. 5

MODERNIZING THE FEDERAL FOOD AND DRUG ACT

The present Federal Food and Drug Act became law in 1906. It was designed, primarily, to safeguard the consuming public against deception and fraud in the sale of foods and drugs passing in interstate commerce.

That the enactment has been productive of incalculable good does not admit of rational argument. It has operated to prevent the sale of many and various goods dangerous to the public health. It has, to a large degree, served to correct many cases of flagrant deception in the labeling of drug products.

Equally evident is it that the law, as it now stands, is grossly inadequate for the proper protection either of the public health or the consumer's purse. Twenty-seven years of enforcement have revealed many weaknesses in the statute which defeat full accomplishment of its purpose. Some of these weaknesses are inherent in the original limitations of the law itself; others have grown out of changed and changing conditions. Both the food and drug industries have expanded tremendously since 1906. The intervening 27 years have witnessed a gradual transfer, throughout the Nation, of food preparation from the kitchen to the factory. Methods of transportation and advertising, particularly the latter, have changed enormously. New provisions are required to meet the new conditions.

The Department of Agriculture, at the direction of the President, has drafted a bill designed to plug the loopholes in the existing law and to modernize it, to the end that it may prove a more effective instrument against present-day abuses. This new draft was introduced in the upper Chamber of Congress last June by Senator Royal S. Copeland of New York, and is known as "S. 1944." While preserving all the worthy features of the present law, it strengthens and extends the existing enactment in many important particulars. Among these are:

JURISDICTION OVER FALSE ADVERTISING

Many foods and drugs carry no false statements on their packages, but their advertising is blatantly misleading. Legal actions against false labels result merely, under the law as it now exists, in correcting the labels; continued deception of consumers may be and often is accomplished by advertising the false claims formerly made on the labels.

INCLUSION OF COSMETICS

The health of many persons is impaired by poisonous cosmetics, for the popularizing of which false labels and deceptive advertising are frequently and largely employed. The present law has no jurisdiction over cosmetics. The bill now pending will correct these evils.

BETTER CONTROL OF POISONOUS FOODS

The present law contains no provision against poisons in foods, unless the poisons are added. The bill now pending prohibits the sale of dangerous foods, regardless of whether the hazard is caused by added poisons or otherwise. As the law now stands, the testimony of expert toxicologists must be introduced, in every case, to show that the quantity of added poison is such as may be harmful to health. The proposed legislation authorizes the Secretary of Agriculture to establish, upon expert advice, safe tolerances for added poisons in foods.

MORE ADEQUATE CONTROL OF FALSE CURATIVE CLAIMS FOR DRUGS

Many persons are influenced by false curative claims for drugs to postpone or discontinue rational treatment for serious diseases. Frequently, the disease is thus permitted to progress to a point where illness becomes protracted or untimely death follows. As the law now stands, there is no control over false curative claims in advertising. Even in establishing the case against such claims in labeling which, like advertising, is subject to the present law, the Government must show not only that the claims are false, but that the manufacturer knows they are false. Public protection against this evil is, therefore, inadequate because proof of a manufacturer's actual state of mind is practically impossible to establish. The pending bill prohibits false curative claims in both labeling and advertising. Under it, the Government would not be required to show that the manufacturer knows they are false. Neither would it be required to prove that the therapeutic claims are "false and fraudulent"; it need only establish that claims are contrary to the general agreement of medical opinion.

FULLY INFORMATIVE LABELING OF FOODS AND DRUGS

The existing law, while prohibiting false labeling, does not require the manufacturer to state the whole truth as to what his product is. The pending bill requires that foods be labeled with their common names and that drugs be labeled with the common name of each therapeutic or physiologically active ingredient. This is simply an expression of the right of the consumer to know what he is eating and what he is taking for his ills.

There is no valid reason anywhere why the proposed legislation should not become law; there are many and compelling reasons why it should. It is necessary for the proper protection alike of the consumer and of honest manufacturer and dealer—the former, in his health and his economic welfare; the latter, against unfair and dishonest competition.

Statements of Officials and Individuals Interested in the Passage of S-1944

From C. A. Harper, M.D., State health officer, State Board of Health, Wisconsin:

"I am familiar with Senate bill 1944, and fully in accord with its contents. It will be a godsend if we can get a national food and drug act that will hold up and be in force throughout the United States."

From Jane H. Rider, director of the Arizona State Laboratories, University of Arizona, Tucson, Ariz.:

"In Arizona we are particularly interested in Senate bill 1944, since the regulations relative to foods passed by the Secretary of the United States Department of Agriculture automatically become effective in Arizona. We also hope to interest the State board of barbers and cosmeticians in the features of the bill that regulate the traffic in poisonous cosmetics."

From Verne K. Harvey, M.D., director division of public health, department of commerce and industry, State of Indiana:

"We realize that every person interested in public health should put forth an honest effort to get the new Federal food and drug bill passed."

From H. H. Hanson, State chemist, State board of agriculture, Dover, Del.:

"All food officials should unite in assisting to strengthen the existing Federal food and drug laws. The bill known as the Copeland Bill, S. 1944, has been very carefully prepared, and if passed and approved, would seem to me to be a long step in advance over the present statute."

From E. L. Redfern, chief chemist, State of Iowa, department of agriculture:

"I can assure you that I heartily endorse the resolutions of the Ohio Valley Conference, and I am in hopes that Congress will pass S. 1944 this winter, with as few modifications as possible."

From Ray Murray, secretary, department of agriculture, State of Iowa:

"I can assure you that the division of dairy and food, which is under my personal supervision in this State, heartily concurs in the resolutions as adopted by the Ohio Valley Conference, endorsing S-1944."

From A. M. G. Soule, chief of the division of inspection, department of agriculture, State of Maine:

"As food officials, we should make every endeavor to have Congress recognize and pass the proposed new Federal food and drug bill, and you may be assured that I will work to that end."

From W. M. Allen, food and oil chemist, North Carolina department of agriculture:

"We have looked into Senate bill 1944, and find it is what we feel ought to be passed by Congress, and personally I am going to do all that I can to urge the passage of this bill."

J. D. Mickle, division chief, division of foods and dairies, department of agriculture, State of Oregon:

"In regard to the passage of United States Senate bill 1944, I am deeply interested in the passage of this act and pledge you I will do all within my power to urge the Senators and Representatives of the State of Oregon to vote for the bill."

From Guy G. Frary, State chemist, State Chemical Laboratory, South Dakota:

"I need not tell you that I am fully in sympathy with the proposed revision of the National Food and Drug Act. I feel that we need to secure the enactment of this bill without any serious changes in its contents."

From E. C. Koerth, director of the bureau of food and drugs, State department of health, State of Texas:

"I want to state that I am heartily in accord with the provisions of Senate Bill 1944, and am hopeful of its passage."

From George H. Marsh, supervisor of the division of agricultural chemistry, department of agriculture and industries, State of Alabama:

"We have studied the new Federal Food and Drug Act S-1944. We consider it an excellent piece of legislation. It is in keeping with the times, a progressive act which will enable the Federal Food and Drug Administration to cope with the changes which have come about since the enactment of the present Food and Drug Act, which was passed in 1906. The new act will be of much value in controlling some of the dangerous advertising which is going on throughout this country on foods, drugs, and cosmetics, which badly need to be controlled.

"We have worked under the Food and Drug Act of 1906 for more than a quarter of a century and there have been untold benefits derived as a result of this work. The present Food and Drug Act of 1906 was a wonderful piece of legislation when it was enacted, but things have changed during the last 25 years in this country, as well as throughout the world.

"There has been a complete revolution in the industrial world in processes and methods of manufacturing which had never been dreamed of when the Food and Drug Act of 1906 was passed. In the new common place practices, naturally it is not possible to cope with these new processes and methods, practiced under the present Food and Drug Act.

"The several States' Food and Drug Laws, are fashioned after the Federal Food and Drug Act of 1906, which is for the sake of uniformity in the enforcement of food and drug laws. A new food and drug act such as S-1944, would strengthen the food and drug law in practically all of the States. We consider the passage of the new Federal Food and Drug Act, a much needed piece of constructive legislation and we hope that Congress will see fit to pass it at as early a date as possible after convening in its next session."

W. F. Hand, State chemist, department of chemistry, Mississippi State College:

"Those who are familiar with the present Food and Drug Law and who have had an opportunity of studying the clear and inclusive requirements of the new legislation proposed will be particularly impressed with the excellent use which has been made of the precepts of a long and successful experience in food law administration.

"The fine pioneering work of a generation ago is now in urgent need of revision and extension to bring it in closer harmony with social and industrial change. It cannot but be admitted that this undertaking has been thoroughly accomplished in the Copeland bill which will become, if enacted, a trustworthy guardian of the public health and an assurance of fair trade practices and policies in the food and drugs industries."

J. W. Sample, superintendent and State chemist, Nashville, Tenn.:

"Present food and drug law inadequate to protect consumers and honest manufacturers. Tugwell bill is fair to all, workable, and fills long-felt need. Will greatly strengthen State food and health departments. Bill as a whole heartily approved by Tennessee Food and Drug Administration."

From Arling Gardner, deputy commissioner of agriculture, department of agriculture, dairy, food, and oil division, State of Wyoming:

"I wish to assure you that this State is vitally interested in the proposed changes in our national food and drug laws. We are making our desires known relative to the proposed changes to the officials in Washington through our Wyoming Senators and Representatives."

From G. N. Bilby, M.D., State health commissioner, department of public health, State of Oklahoma:

"I think that it is time we were making a change in the Federal food and drug law and improving it, as many things have come up since the old law was passed."

From Arthur E. McClue, M.D., State health commissioner, State of West Virginia:

"It is highly desirable that the Federal food and drug bill, S. 1944, should be enacted, and I will request our Representatives and Senators to give it their support."

Statement from Mrs. E. H. Heller, president of the Kentucky Federation of Women's Clubs:

"Much is being written and said about the proposed pure food and drug law, how it will require honest and informative labeling of all food stuffs, cosmetics, and drugs with the whole truth instead of a half truth as at present; how it will protect the consumer from false advertising; how it will provide that the standard of the product shall be on label; how it will establish a 'minimum tolerance' of the poisons which naturally occur in some foods, or are required in the course of growth and manufacture; how it will require full package and bottle content, doing away with bottles with sunken panels or thick sides; how it will protect women against unsafe cosmetics. In other words, it guarantees honest goods for the consumer.

"The club women of Kentucky are deeply interested in the passage of this bill, which so vitally affects the housewife. The club women have had the opportunity of having it explained to them this fall, as representatives of our State board of health spoke at all 11 district meetings. These meetings are held once a year for the club women of each district to get together; therefore, large groups were reached. In this way every section of the State has become interested in the passage of Senate bill 1944."

Editorial appearing in the Herald-Post, Louisville, Ky., December 1, 1933:

"Why We Need a Pure Food and Drug Law", by Mrs. E. H. Heller, president, Kentucky Federation of Women's Clubs.

"Time makes ancient good uncouth" might well be written about our present food and drug law.

Many people fail to realize that this statute has become obsolete and no longer provides protection to the consumer.

Back in 1906, after Dr. Wiley's Pure Food and Drug Law was drafted, everybody felt perfectly safe, as it was thought this law provided that when a manufacturer truthfully labeled his product that the consumer was sufficiently protected.

But who in 1906 could have predicted the phenomenal growth of modern advertising through magazines, newspapers, billboards, the radio; hence, no provision was made to control advertising.

It seemed sufficient then, in order to protect the consumer against dishonest claims, to require only that the label tell the truth, but today because of this limitation in Dr. Wiley's law, a manufacturer who labels his products truthfully can at any time build up a demand for it through false advertising of the egregious sort, making claims at variance with the statement on the label.

Cosmetics were a comparatively unimportant item when Dr. Wiley's law was passed, but today the manufacture of cosmetics is an industry that closely affects the health and pocketbook of millions of consumers. There are certain types of "beautifiers" such as skin bleacher, freckle remover, hair dyes and tonics, and depilatories, which contain dangerous ingredients that sometimes cause serious skin poisoning, yet the Government cannot protect the consumer under the present law.

The new Federal Food and Drugs Act which was introduced in the Senate by Senator Royal S. Copeland of New York on June 12, 1933, as Senate bill 1944, is designed to correct the weaknesses in the present statute that have been brought to light through interpretation by the courts, and further to provide authority for the control of new conditions.

All false and misleading advertising of food, drugs, and cosmetics through any medium whatever is prohibited. The provisions concerning labels are considerably strengthened so that these labels must be definitely informative and the consumer may know exactly what he is buying and how he can use it with complete safety.

More drastic penalties for violation of the act will insure more faithful observance of the law and a greater protection for the buyer.

Under the new law the protection of the consumer is paramount. The ethical manufacturer is also protected, and there are many such manufacturers who will

be delighted to have this bill passed. It is only the manufacturer who makes the false claims who will oppose it.

The fate of this bill rests with the public, for whose protection it is designed.

Statement from Louise Morel, chairman of public welfare and chairman of public health, Kentucky Federation of Women's Clubs:

"The Women's Clubs of Kentucky that have had the opportunity of studying the bill S. 1944 are, without reservation, endorsing it in a very emphatic manner and are asking their Senators to pass same.

"The women know the value of publicity that produces information that serves to guide them to their purchases of foods, drugs, and cosmetics.

"There is one section in the new food and drugs bill that contains more potential dynamic power than any other, section 21, relating to publicity. This section provides that 'The Secretary shall cause to be published periodically a report of all judgment decrees and orders which have been rendered, all proceedings instituted and seizures made, including the nature of the charge and disposition thereof.'

"What is more to the point, it also provides that 'The secretary shall cause to be disseminated such information regarding any food, drug, or cosmetics as he deems necessary in the interest of public health and for the protection of the consumer against fraud'—.

"We believe that this section is one of the most valuable in the entire act."

Resolutions adopted by the Women's Auxiliary to the Kentucky State Medical Association in annual session at Murray, Ky., September 1933:

"Whereas the Food and Drug Administration of the United States Department of Agriculture, acting under the instruction of President Roosevelt in his program for the new deal, has prepared a new food and drug law which has been introduced as Senate bill 1944 by Senator Copeland, of New York, in the Congress of the United States; and,

"Whereas this law, as prepared by the Administration, will protect the consumer from menace to health from misbranded and falsely advertised foods, drugs, and cosmetics and will provide such penalties for the violation of the law as are not now provided: Now, therefore, be it

"*Resolved*, That the members of the Women's Auxiliary to the Kentucky State Medical Association make every effort to further the passage of this bill, S. 1944, by urging individual Members of Congress to vote for its passage, and, further, be it

"*Resolved*, That the auxiliary urge all members as individuals, and in organizations with other friends, to study and work for the passage of this bill, S. 1944."

Resolutions adopted by the American Public Health Association in annual meeting at Indianapolis, Ind., in October 1933:

"Whereas the present Federal Food and Drugs Act has brought a high measure of protection to the American public through its faithful enforcement by the Food and Drug Administration officers and

"Whereas due to changing methods of manufacture and distribution of foods and drugs the act needs revision to maintain and increase public protection: Therefore be it

"*Resolved*, That we, the members of the American Public Health Association:

"(1) Express our confidence in the intent and purposes of the principles of the proposed revision of the Federal Food and Drugs Act now before Congress for action; and

"(2) We solicit the support of all members of this association to secure the enactment into law of the objectives of this revision and

"(3) that this expression of the views of the association be made a part of the record of the association."

Statement published in the Health Notes, the official monthly bulletin of the State Board of Health of Florida, November 1933:

"New Federal Food and Drugs Act.

"A matter which should be of great interest to all interested in public health work is Senate bill S. 1944, introduced by Senator Copeland just before the adjournment of the last Congress. This bill, known as the new Federal Food and Drugs Act, will have active consideration by the next Congress.

"In the bill are included many provisions intended to expand, supplement, and strengthen the present Federal Food and Drugs Act. The bill provides for control of advertising of all foods, drugs, and cosmetics. The present law has no jurisdiction over advertising, outside of the actual package label. It will prohibit the sale of dangerous cosmetics and will require all cosmetics to be truthfully labeled. Dangerous cosmetics are not restricted in any manner under the present law.

"The measure will authorize the Secretary of Agriculture to establish standards for foods having the force and effect of law and will require more fully informative labels on foods, drugs, and cosmetics. It will also prevent the sale of drug products for self-medication for diseases where such use may be dangerous. It will prevent either direct or indirect representation of the effect of drugs which is contrary to the general agreement of medical opinion, and will also require products labeled as 'antiseptics' to be really antiseptic when used according to directions.

"Of great interest to health workers and consumers is the fact that this bill will provide a means for control of sanitary conditions of manufacture, processing, and packaging of food products, a factor lacking in the present law.

"It will require label and advertising statements claiming special nutritional value for food products to be literally true and will outlaw all manner of deceptive packages, including slack-filled and deceptively shaped ones."

[Editorial from Courier Journal, Louisville, Ky., Dec. 10, 1933]

THE FOOD AND DRUG BILL

Secretary of Agriculture Wallace has added his official endorsement to the Copeland bill to strengthen the Pure Food and Drugs Act. When Senator Copeland introduced it last June it was announced that the bill was submitted by direction of President Roosevelt, but it was lost in the legislative stampede during the last days of the session. Prof. Rexford Guy Tugwell, one of Secretary Wallace's assistants, is generally credited with being its author.

Briefly, the Tugwell or Copeland bill is designed to modernize food and drug supervision by extending to advertising, by radio or the printed page, the same provisions that now restrict labeling, and to put the cosmetics industry also under supervision. In the case of patent medicines, the therapeutic claims must conform to the general agreement of medical opinion. For instance, drugs that are mere palliatives must be labeled, and advertised, as such and not as cures. Concoctions containing narcotics must contain a warning to that effect. Germicides must tell how much application is necessary to kill the microorganisms. The labels hereafter must tell the exact amount of a bottle's contents. Labels on food packages also must be fully informative as to their content.

Of course, the patent medicine manufacturers call the bill "the greatest legislative crime in history," and there is some protest by food processors, but the cosmetics industry welcomes regulation as a whole because of the many cheap and dangerous products on the market. Publishing, advertising, and radiocasting interests have demanded the reform of shady advertising habits because of the reflection upon them when deceit or fraud is practiced. By the terms of the bill, the regulation of which is in the hands of the Secretary of Agriculture, those who pay for the advertising are held responsible for misstatements.

Professor Tugwell had a "chamber of patent medicine horrors" at the Century of Progress. Among the displays, a fair sample of its contents, was an alleged diabetes cure, selling at $12 a bottle, and beside it a column of testimonials by persons claiming to have been cured. Paralleling the testimonials were death certificates of the individuals in question, showing each to have succumbed to the disease they claimed to have been healed of.

The howls of the nostrum manufacturers prove the deadly accuracy of the Tugwell thrusts. The greatest objector to the restriction on nostrum advertisements is the country weekly, whose rural subscribers constitute the bulk of patent-medicine dupes. If the people are undeceived, the manufacturers will lose sales.

The CHAIRMAN. Next we will hear from Mrs. Bannerman, legislative chairman, National Congress of Parent-Teacher Associations.

STATEMENT OF MRS. WILLIAM T. BANNERMAN, LEGISLATIVE CHAIRMAN, NATIONAL CONGRESS OF PARENTS AND TEACHERS

Mrs. BANNERMAN. My name is Mrs. William T. Bannerman, chairman of the committee on legislation of the National Congress of Parents and Teachers.

The National Congress of Parents and Teachers has as its purpose child welfare in school, church, home, and community.

We have organizations in 48 States, Hawaii, and the District of Columbia, 20,000 local associations, with a paid membership of approximately 1,500,000.

We do not claim to represent any particular interests, since our purpose is child welfare.

I suppose that there may be in our organization capitalists, professional people, laborers, manufacturers, advertisers, and people of all types of occupation. Since our purpose is child welfare, I think it will be conceded that self-interest is not our motive in supporting this bill.

We have had for more than thirty years, a definite health program for children which is carried on both in the home and in the school. We believe that there is just as much need for the protection which this legislation is designed to afford, as there is for the protection of an army and navy for other types of enemies to life. The National Congress of Parents and Teachers indorses general principles with regard to health, schools, etc., at its annual convention; specific bills which are in conformity with these principles are indorsed by its Board of Managers. S. 1944 was unanimously indorsed by the N. C. P. T. Board of Managers on Sept. 21, 1933. We urge its early enactment into law.

The CHAIRMAN. Thank you, Mrs. Bannerman.

Mrs. Franklin W. Fritchey, of the Maryland Home Makers' Association.

STATEMENT OF MRS. FRANKLIN W. FRITCHEY ON BEHALF OF THE MARYLAND HOME MAKERS' ASSOCIATION

Mrs. FRITCHEY. Not long ago I was asked if I was any relation to Barbara Frietchie, of Maryland. I said that I was the mother of Barbara Fritchey, and the gentleman said, "You certainly have held your age."

Dr. Copeland, and members of the Committee, I represent a group of women who have been studying foods. That has been our real work for several years.

We felt that as a home makers' group we would take up consumer problems, and so the first thing in which we became interested was foods.

We had the great pleasure of working with Dr. Wylie, and through our contact with Dr. Wylie we just stayed on foods. We found that it was an unlimited field, and a great work for us to do.

So we have taken up the study of legislation with regard to foods and, of course, that took us into the study of the pure food laws.

We knew that Dr. Wylie had had a tremendous fight, and I believe even a bigger one than Dr. Campbell and all of you are having here today, but he fought bravely, and he had the backing, at that time, of many women and women's organizations.

Necessarily, then, we became interested in the new bill. Last spring I compiled and published a booklet on the origin of the pure food laws and the progress in Federal food control and I have distributed 75,000 copies during the Century of Progress this summer.

I have met thousands of women and talked to them, and I felt that this book would be an education to them along the line of what the pure food laws were; women knew so little about them, and it would prepare them so that they would understand the new law.

I am receiving letters from almost every State asking me for more information on the pure food laws and how to prepare programs before women's clubs on that subject.

We find that women's responsibility as consumers and as the world's largest buyers leads them to realize their power as purchasing agents for their families, and they are beginning to take their jobs more seriously and beginning to make their power felt, as it should be.

We must recognize in these days of the so-called "depression" and the New Deal that the good of the consumer and the good of industry are bound up together.

Right here I might say that I feel as the previous speaker said, that consumers should be represented in the conferences of you men who are preparing foods for us, as to what we would like, what size jars, what quality, and so forth and so on.

I do not think that it would be amiss for us to sit around a table together and then maybe we would not have to have so many pure food laws.

We find, too, that the home is being revitalized; there is a lot of professional skill going into the home. We are getting new techniques into the homes, scientific management, and we are all interested in this institution called the home.

Economically, the world cannot function unless women make some kind of productive return, and so we are necessarily interested in the new food law.

It is a measure that is going a great deal farther than the present law, and we do endorse this bill, with a few reservations.

We do want honest advertising. One man said today he was spending—he was afraid to tell how much, but we know it is in the millions—we know the journals and magazines and newspapers are only for women, outside of the front page.

All of these items, from sauerkraut to fur coats, are for us, and when we know that you are going to be honest advertisers, then we are going to have more confidence in your goods and you.

In other words, if we were all on principle, and principle means honesty, we are all going to be a happy family, we are going to be happy and work with you, and you are going to be happy to have us work with you.

We women have always bravely faced the daily task of providing food for the health and well-being of our families. Not so many years ago the problem was to find the food. Now the problem is to choose from the vast markets of the world, and how is she going to choose unless she has correct labels on her packages and on her cans?

We welcome the McNary-Mapes amendment, because it was a great help to us.

It was sponsored, we found, through the National Canners' Association, and when we found that, we consulted with them to what extent we could believe them, and what faith we could have in their labels, and for that reason we feel that this new law, which suggests Grades A, B, and C, would be a wonderful thing for all of us if it could be enforced.

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But, can it be enforced? That is the thing for us to take up and work out to the satisfaction of both the consumer and the producer.

It might leave a loophole where some manufacturer or producer who did not want to put out his good string beans or a good can of peas, might just slip one over on us, and we have had that done long enough.

Let us consider that as one of the measures of the bill to be reconsidered.

We also know that Dr. Wylie worked for years to take out adulteration and poisonous ingredients in foods. We find now with this new bill that canned foods are now sterilized and are being put in airtight containers. They do not use preservatives any longer.

We find that Dr. Wylie was finally considered the best friend the food industry ever had, although they thought at first that he was their worst enemy.

Many of you men will find that this bill is going to be your friend and not your enemy.

The last thing we have to suggest on this bill, as I only have one more minute, I believe, is that we are just in doubt about whether we are giving too much power to one man in this bill.

Let us consider that, how that can be handled.

We had an example of that with the former Secretary, in bringing out a regulatory amendment just a few weeks after Dr. Wylie's death in the case of the corn sugar, where he said it could be used in foods and not put on the labels.

If the secretary could have that power, he could say you could put cottonseed in butter and not put it on the label, and so forth and so on.

So, those are things that we women are anxious to watch and see that that kind of thing does not happen.

I may not have studied the bill correctly, but those are the things I would like to have considered.

I had other things that I would like to speak about, but the home makers are the consumers, and we want the best legislation for all concerned.

The CHAIRMAN. Thank you very much.

I will call now on Mrs. Malcolm McCoy, of the New York Federation of Women's Clubs.

STATEMENT OF MRS. MALCOLM McCOY, PRESIDENT, NEW YORK CITY FEDERATION OF WOMEN'S CLUBS

Mrs. McCOY. Senator Copeland and members of the Committee, before I speak in my official capacity, I wish to speak as a consumer purely.

I feel that as a consumer certainly the interests of all the consumers who have been represented here today have been met very fairly by the chairman and his committee, and that certainly we have had every consideration as well as have had the various industries which have been represented. [Applause.]

I have not the opportunity to speak for myself, but I must speak as my organization has mandated and, therefore, I will read a few remarks that I have to make.

I represent 350 clubs, large and small, which are composed of approximately 30,000 to 40,000 women in New York City.

The New York City Federation of Women's Clubs at the convention held October 27, endorsed the principle and general purpose of the pending Senate bill 1944, and mandated its president to attend the present hearing in order to obtain accurate information on all phases of the bill as presented in the arguments pro and con.

The Federation has learned thta it is unwise to endorse any bill in its entirety or otherwise.

Pending legislation is sometimes difficult to recognize when it is finally adopted, and many bills carry riders which the Federation cannot possibly endorse.

My organization would be the last at a time of such economic stress to wish to be unfair or to interfere with the success of legitimate business of honest manufacturers and dealers in foods, drugs, and cosmetics.

We do insist, however, upon the protection of the consumer, and we have, therefore, endorsed the general purpose and principle of the bill.

I have here the resolution which I will not take your time to read, but I will submit it:

(Resolution adopted unanimously by the New York City Federation of Women's Clubs, Mrs. Malcolm Parker MacCoy, President, on October 27, 1933.)

Whereas the Federal Food and Drugs Act adopted on June 30, 1906, has resulted in a great improvement in the purity of foods and drugs sold in the United States, but experience has shown that there are still products freely sold which constitute a menace to the health of the consumer or user, and are not subject to the provisions of the present act, and furthermore, the truthful labeling of many foods and drugs is nullified by fraudulent advertising not subject to the present law, and

Whereas, a bill now pending in Congress, known as Senate bill 1944, is designed to preserve all the worth-while features of the present law, such as the prevention of adulteration and misbranding of foods and drugs, and will extend the scope of the law so as to include cosmetics, and also contains provisions designed to insure the truthful advertising of foods, drugs, and cosmetics.

Resolved, That the New York City Federation of Women's Clubs in convention assembled endorse the general principle and purpose of Senate bill 1944, introduced by Senator Copeland in the Senate of the United States, which will be under consideration by Congress at its next session; and

Be it further resolved, That a copy of this Resolution be sent to Senator Copeland and to the Congressman of each district in the five boroughs of the city of New York.

Presented by the Home Makers Forum, Inc.

Endorsed by the Department of Citizenship, Elise Brown, chairman.

ELENORE F. HAHN,
Mrs. OTTO HAHN, *President*,
Home Makers Forum, 640 Riverside Drive, New York, N.Y.

The CHAIRMAN. I have here the names of eight persons, and I shall pass them to the record.

They are persons who asked to speak and who have disappeared.

I do this because I want to make clear that everybody who has asked to speak has been given the opportunity and some others besides.

Kenneth Collins, Washington, D.C., National Retail Dry Goods Association.

General Gillette, Troy, N.Y., William W. Lee Co.

W. W. Schneider, Cincinnati, Ohio, Monsanto Chemical Co.

Daniel R. Forbes, National Preserves Association; Eastern Cider Vinegar Manufacturers Association; the American Vinegar Association.

R. M. Allen, president, the Vitamin Food Co.

A. M. Loomis, secretary, National Dairy Union.

W. F. Jensen, manager, American Association of Creamery Butter Manufacturers.

Stanley Smith, Marinello Co.

We have now 19 minutes before adjournment. I desire, if possible, to leave the last 10 minutes free for one who has had much to do with the preparation of the bill, and I say with regret to the three other gentlemen that the time is limited and if, for any reason, you cannot say all you want to, if you have prepared addresses—I do not know about that—please hand them to the stenographer, and they will appear in the record as if they had actually been delivered here.

The first one is Mr. Edward L. Greene, of New York City, general manager of the Better Business Bureau.

Mr. Greene.

STATEMENT OF EDWARD L. GREENE, GENERAL MANAGER, NATIONAL BETTER BUSINESS BUREAU, INC.

Mr. GREENE. Mr. Chairman, my name is Edward L. Greene, general manager of the National Better Business Bureau; our purpose is to attempt to correct such practices in advertising, specifically national advertising, as are against public interest.

We are a voluntary regulatory body, and, as such, we are extremely interested in the proposed legislation.

We have in our experience realized that regulation under the best circumstances is not an exact science.

It is very difficult to please everybody, and with matters as controversial as those which this bill seeks to remedy obviously there is going to be plenty of discussion and difference of opinion.

But I am very much convinced, Mr. Chairman, that there is one common ground that appears to reach through this whole group, and that is that you are all firm in your belief and determination that the false advertising practices or those which actually damage the public shall be remedied.

I have great confidence also in the wisdom of this committee in selecting the various suggestions that have been made to you, and from them to prepare a bill which will serve the purpose of all of us.

I am primarily concerned at this time in suggesting a point on the administration of the bill.

Every law is effective to the degree that it is influential.

I am, therefore, suggesting, and will subsequently present, a definite amendment to the bill, that will provide for self-regulation of the industry.

Now, I recognize that at the present time the industry has the right of self-regulation, and I am taking an active part in it myself, but I believe that to add such an amendment would give to any person evidence of the Government inviting industry to cooperate with it and keep its own affairs above criticism and in the public interest.

Therefore, Mr. Chairman, I will submit this in a definite, suggestive form sometime in the very near future.

The CHAIRMAN. We will be very glad to receive it. Thank you very much, Mr. Greene.

The amendment mentioned by Mr. Greene, with explanatory statement, follows:

I respectfully request the consideration of your committee of the following proposed amendment to Senate bill S. 1944:

To aid in the administration of this act, associations or groups may present plans for self-regulation of their advertising practices to the Secretary of Agriculture, which he shall accept subject to the authority granted under the act provided that the Secretary shall find said groups or associations to be truly representative of their industries and that said plans tend to effectuate this act and are not designed to promote monopolies or to eliminate or oppress other enterprises.

I offer this proposed amendment in behalf of the National Better Business Bureau, Inc., a nonprofit corporation located in the city of New York, which was established 22 years ago by the Associated Advertising Clubs of the World, now known as the Advertising Federation of America. The National Better Business Bureau is a membership organization composed of over 400 business firms consisting of national advertisers, publishers, and advertising agencies. Its purpose is to promote honesty and fairness in advertising and selling. It endeavors to fulfill this purpose by fostering ethical business practices and the discontinuance of unethical practices through the voluntary cooperation of the offenders.

The principal reason for the creation of the bureau in 1911, known at that time as the National Vigilance Committee of the Associated Advertising Clubs of the World, was to combat the same type of advertising which this bill is intended to control and which at that time was much more prevalent. The Pure Food and Drugs Act of 1906 had been in operation for several years but it had not been successful in circumventing the numerous charlatans who were advertising bottled cures for tuberculosis, cancer, and other serious ailments. This exploitation of the public was induced through advertising of the rankest sort and the members of the advertising industry recognized that the public health was being jeopardized and that advertising was degraded and losing efficiency because of such abuses. They created the bureau with the intention of doing whatever they could collectively to protect their interests and the public's from those who used advertising to deceive and defraud.

In this capacity, we have had numerous occasions to contact various law-enforcing bodies, including those in charge of the administration of the Pure Food and Drugs Act, and various State and city health officials, particularly the commissioner of health of New York City. I am pleased to say that we have always received splended cooperation from these Government agencies and we have had occasion many times to submit information that would be helpful to them. Owing to our being in New York City, we have our closest contacts with the New York City Health Department and the New York office of the Federal Food and Drugs Administration. We are conversant with many of the advertising practices which the proposed act undertakes to correct, and we have a practical understanding of the many difficulties involved in obtaining satisfactory regulation of advertising in the broad field which this bill covers.

In offering this amendment, we have no desire to in any way interfere with the administration of this act. However, we believe that with the inclusion of an amendment providing for self-regulation, the administrative authorities set up by law will gain the cooperative effort of many of those for whom the law is intended to regulate. The result of this joint regulation consisting of the Government and the cooperative interests of the advertising industry, will be to their mutual interest and provide a greater scope of protection for public health.

I feel certain that my appeal amounts to a sympathetic response to President Roosevelt's request that Government and industry cooperate in their mutual interest and thereby provide the means to obtain a more wholesome industry in the public interest.

We recognize that the right to practice self-regulation within the law exists despite the absence of a provision specifically permitting it. So the question might readily be asked—"If the opportunity for self-regulation exists without incorporating it in this law, why make the suggestion that it be included?" Our answer is that we believe all laws are effective to the extent that they are influential, and that the more law enforcement agencies can obtain the cooperation of those for whom the law is intended the more substantial will be the enforcement of the law.

By making provisions for self-regulation you provide the ever present invitation to those for whom the law is intended to cooperate in their own interests with the administrative authorities to obtain the best possible regulation. To the extent that practical self-regulation programs are put into effect, the public is the beneficiary of the purpose and intent of the law, and likewise honest advertising interests are protecting themselves against unfair competition. To the same extent the Government is relieved of the cost and burden of regulation.

The matters which the proposed advertising sections undertake to correct, generally speaking, divide themselves into two classes. One consists of the advertising of products which are harmful to public health or are exploited in such a manner as to invite the public to jeopardize its health. Such products and such advertising represent a small percentage of the whole, nevertheless they constitute a serious public menace and should have the prompt attention of the Government.

The other group will be made up of the advertising of products which serve a useful purpose but which are advertised in a manner which has the capacity to mislead. Such transgressions could in most instances be corrected by suggestion, and close observation and contact with advertisers in this field would tend to keep the transgressions reduced to the minimum.

We believe the suggested amendment would encourage the advertising interests included in the second group to set up plans of self-regulation that would prove very helpful in cooperation with the Government to provide the widest possible protection to public health that the proposed law undertakes to establish.

Referring again to President Roosevelt's appeal for cooperation between industry and the Government, we submit that the proposed amendment will provide the means for the industries affected by this bill to help answer the request of our President in a practicable manner.

STATEMENT OF LOUIS ROTHSCHILD ON BEHALF OF THE NATIONAL ASSOCIATION OF BETTER BUSINESS BUREAUS

Mr. ROTHSCHILD. Mr. Chairman, my name is Louis Rothschild, director of the Washington Better Business Bureau, appearing on behalf of the National Association of Better Business Bureaus, which includes 50 such orgnaizations in the various cities, of which the National Better Business Bureau is a member.

Our organization supports the general principle of this legislation. It was considered at the last annual convention, where this resolution was adopted.

Resolved, That it is the unanimous opinion of the 19th annual conference of the Affiliated Better Business Bureaus, Inc., that there is a need to enlarge the scope of the Federal Food and Drug Act and that the effort being made with that objective in view by the present administration be endorsed and hereby so endorsed.

The CHAIRMAN. The next speaker comes from my own native State, Michigan.

I am sorry to have to limit any Michigan man. I have always resented it myself, when I have been put under limitation.

Mr. Frank Gerber, from Michigan, representing the National Canners' Association.

STATEMENT OF FRANK GERBER, ON BEHALF OF THE NATIONAL CANNERS' ASSOCIATION

Mr. GERBER. Mr. Chairman and members of the committee.

My name is Frank Gerber, of Fremont, Mich., a practical canner, and former president of the National Canners' Association and at present a member of its administrative council.

The National Canners' Association was organized in 1907.

It represents packers of more than 60 percent of the canned foods produced in the United States, not including milk.

Its membership is about 650 firms, operating 1,070 plants.

The association is in full sympathy with the purpose of the Department of Agriculture to correct such deficiencies as have been found to exist in the present Food and Drugs Act, and the recommendations it presents on behalf of the industry are based upon its desire to assist those responsible for legislation in formulating a measure that will accomplish the purposes desired without imposing unnecessary hardship.

It is the opinion of the industry that many, if not most, of the new or revised provisions embodied in S. 1944 are more directly applicable to products other than foods, and for that reason we earnestly petition that you give consideration to the preparation of a separate food bill. Foods differ as widely from drugs and cosmetics both in nature and in character of control necessary over them that separate legislation would eliminate many of the problems involved in formulating and enforcing a law designed to cover all these classes of products.

The suggestions and recommendations we have to make relate to the provisions as carried in S. 1944. If a separate food bill should be prepared, these suggestions and recommendations we request be embodied in that bill.

As a general amendment, we recommend that wherever the word "health" is used there be substituted the words "public health." The word "health" alone might be interpreted to mean the susceptibility of an individual to injury from a food that may be eaten with impunity by the normal person. Other specific recommendations are as follows:

Section 2 (a), line 2, page 2. Add—

The term "canned food" shall mean all food which is in hermetically sealed containers and is sterilized by heat, except meat and meat food products which are subject to the provisions of the meat inspection act of March 4, 1907 (34 Stat. 1260), as amended, and except canned milk.

The addition of this definition is because of revisions that will be recommended in section 11 of the bill.

Section 3 (a), line 23, page 3. Delete the words "or may be."

Section 3 (a), line 6, page 4. Substitute the word "has" for the word "may have."

The canning industry believes that the determinations provided for in this section should be based upon fact rather than conjecture.

Section 7 (a), line 19, page 8. After the word "food" insert the words "other than canned food." After line 24, page 8, add "If it be canned food and falls below the standard of quality or fill of container, promulgated by the Secretary for such canned food, and its package or label does not bear a plain and conspicuous statement prescribed by the Secretary of Agriculture indicating that such canned food falls below such standard." The addition of this paragraph is also requested because of recommendations that will be made in connection with section 11.

Section 7 (f), line 6, page 9. Delete the phrase "in order of predominance by weight." This phrase is not necessary to accomplish the purpose of the paragraph which, we are advised, is for the protection of individuals suffering from some form of allergy. Moreover, it

would appear to be confiscatory in view of the fact that it required practically a revelation of manufacturing formulae which are the private property of the producers.

Section 11, line 14, page 15. After the word "food" insert "other than canned foods." Insert following section 11 the following as 11 (a):

> Section 11 (a). The Secretary is hereby authorized to fix, establish, and promulgate from time to time reasonable definitions of identity and a reasonable standard of quality and fill of container for each class of canned food as will in his judgment promote honesty and fair dealing in the interest of the consumer, and he is authorized to alter or modify such standard from time to time as in his judgment, honesty, and fair dealing in the interest of the consumer may require. Whenever the Secretary deems that for the purpose of this act any such standard would be established for any canned food, he shall give notice of a proposed standard and of the time and place of a public hearing to be held thereon not less than 30 days after the date of such notice. After such public hearing the Secretary may fix, establish, and promulgate such a standard for such canned food. The standard so promulgated shall become effective on a date fixed by the Secretary, which date shall not be prior to 90 days after its promulgation. Any such standard may be amended or repealed after notice and hearing as hereinbefore provided, and if amended or repealed the amendment or repeal shall become effective in the manner and at the time hereinbefore provided.

The purpose of this proposed amendment is to continue in effect the provisions of the McNary-Mapes amendment to the Food and Drugs Act, which was proposed by the industry itself and enacted with the approval of the Department as a measure directly in the interest of the consumer. When the industry proposed the amendment it recognized the need of a mandatory labeling requirement enforceable under a criminal statute. It desired a mandatory provision because of the need of control over that small minority of manufacturers who, under a system of permissive labeling, might continue practices that are not in the consumer's interest. It desired a provision under a criminal statute so as to give greater strength to the enforcement of the law's requirements.

It desired standards based upon tangible characteristics and qualities susceptible of accurate determination or measurement rather than upon personal judgments, opinions, or tastes, because of the difficulties and dangers involved in the enforcement of a criminal statute upon the grounds of personal opinion. To appreciate the truth and force of this statement it must be remembered that in connection with canned foods there are certain undefinable elements, and elements of major importance, such as flavor and appearance, which it is impossible to describe with the degree of accuracy necessary in connection with enforcement of a criminal statute. It desired a law that, while not attaining immediately the whole purpose of completely informative labeling, would affect improvement and thorough actual experience enable the industry and the Government to extend the program for better labeling. It desired, above everything else, to secure a law that could be and would be enforceable, rather than a law the enforcement of which would prove unfeasible and thus open the way to abuses more injurious to both the industry and the consumer than existed under former legislation.

For these reasons the industry earnestly requests the retention of the McNary-Mapes provisions, in the belief that they represent a feasible, practical method of working out a solution of the labeling question as applied to canned foods, and that provisions going beyond

the McNary-Mapes requirements and seeking to attain an immediate ideal solution of the problem will prove ineffective and unenforceable, and thus simply delay the improved conditions desired by both the industry and the consuming public.

Section 12 (a), line 6, page 16. Delete words "the Secretary finds that"; line 12, page 16, delete word "he" and insert the word "are." These revisions are recommended in the belief that action by the Secretary of Agriculture should be based upon established facts rather than upon opinion.

Section 13 (a) (2), lines 22 and 23, page 17, Delete the words "methods, processes." It is recommended that these be eliminated because their inclusion would give an opportunity for the acquirement of secret and confidential procedures which are not necessary to accomplish the purposes of the Act, and the dissemination of which would be greatly to the disadvantage of the manufacturer.

Section 13 (b) (1), line 10, page 12. Delete the words "methods, processes" for reasons above stated.

Section 17 (b). We recommend that the minimum fines provided for in lines 7 and 10, page 24, be eliminated. As written, the bill makes it mandatory to assess a heavy fine for a possibly trivial offense. It is believed that the penalties for trivial offenses should be less severe than are appropriate for offenses of a graver nature. Moreover, there will be difficulty in obtaining a conviction where conviction carries a comparatively heavy fine for an offense that may not be of a grave character. We also recommend the addition to this paragraph of a provision substantially the same as in the present Food and Drugs Act (section 2) relating to foods that are exported, to read as follows:

> Provided that no food not adulterated according to Section 3 (a) shall be deemed misbranded or adulterated within the provisions of this act when intended for export to any foreign country when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if such food shall be, in fact, sold or offered for sale for domestic use or consumption, then this proviso shall not exempt such article from the operation of any of the other provisions of this Act.

Section 18: It is the feeling of the industry that section 18, which makes no distinction between acts that are willfully criminal or due to criminal negligence, and acts that are inadvertent or accidental, may impose undue hardship upon officials and others who are endeavoring in every way to comply with the law.

Section 21: We recommend that the words "and for the protection of the consumer against fraud," lines 2 and 3, page 29, be eliminated. The industry believes that the dissemination of precautionary information is justified when questions of public health are involved, but does not believe that beyond this there should be authority by publicity in advance of the findings of fact.

Section 22: We ask the elimination of this section, as serving no useful purpose so far as canned foods are concerned. It seems futile and undesirable to set up machinery for certification of unenforceable definitions.

To the extent that certification of quality standards for canned foods in connection with wholesale transactions is desirable, which desirability is not here questioned, the provisions of the warehouse act are available. This act provides for Federal examination of submitted samples and grade certification according to standards

established by the Bureau of Agricultural Economics, and also provides for voluntary cannery inspection and certification service. It is understood that to some extent canners have availed themselves of these services and facilities with satisfactory results in inter-trade transactions.

A certain small portion of the canning industry believe that the Bureau of Agricultural Economics grades are as suitable for enforcement purposes under a criminal statute as under civil statutes, and may appear as active proponents of section 11 and section 22 of this bill as drawn; but the governing board of the National Canners Association rightly holds that experience and evidence cannot be ignored.

There can be cited convincing public statements of informed and responsible officials to fully substantiate what we have said respecting the limitations in the matter of grade definitions of canned foods. To the extent of such limitations the folly and futility of idealistic and unenforceable laws must now be, as never before, apparent.

Section 23 (a), line 5, page 30. Delete the words "he may deem" and substitute "are"; lines 11 and 12, delete words "they may deem" and substitute the word "are." This recommendation is in line with the previous recommendation as to section 3 where it was stated that determination should be based upon facts rather than upon conjecture.

Section 23 (c), lines 2, 3, and 4, page 31. Delete last sentence of paragraph. The elimination of this sentence is requested because of recommendations hereafter to be made.

Section 24. We recommend that section 24 be eliminated from the bill. This section gives the consumer no rights which he does not already have under other legislation and the relatively drastic provisions of this bill will doubtless invite an increase in the fraudulent claims for injury which have been increasing at an alarming rate, and, in certain sections, constitute a racket.

Add new section to constitute section 27 as follows:

Section 27 (a). In any action suit or proceeding involving any regulation made, promulgated, or prescribed under this act, such regulation and any evidence considered by the Secretary and any findings made by the Secretary may be reexamined by any court as to any question of fact as well as law.

(b). In any proceeding involving the issue, renewal, suspension, or reinstatement of any permit under this act, or in any other action, suit, or proceeding involving the rights of any person affected by this act or any action taken thereunder, any action by the Secretary, any evidence considered by the Secretary, and any findings made by the Secretary, may be reexamined by any court as to any question of fact as well as law.

The addition of this section is recommended as a precautionary safeguard against possible misuse of delegated powers.

The CHAIRMAN. Thank you very much.

I will call upon Mr. Bruce Kramer at this point.

STATEMENT OF BRUCE KRAMER ON BEHALF OF THE DRUG INSTITUTE OF AMERICA

Mr. KRAMER. Mr. Chairman, I do not desire to discuss the measure before the committee but, for the purpose of the record, as the counsel for the Drug Institute of America, an organization comprising a membership of approximately 40,000 units in the industry, I desire to have the record show that the Drug Institute of America endorses the views so ably and forcibly expressed by Dr. Beal during his presentation to this committee.

If the record will so show, I will conserve the rest of your time.

The CHAIRMAN. Thank you very much, Mr. Kramer.

The next speaker will be David F. Cavers, professor of law at Duke University.

STATEMENT OF DAVID F. CAVERS

Mr. CAVERS. Mr. Chairman, my name has been indicated. My connection with this measure arises from the fact that I was requested by Assistant Secretary Tugwell to join in a group which assisted in the drafting of this measure which Senator Copeland introduced as S. 1944.

I am sure all of us who participated in that work feel that we have had presented yesterday, this morning, and this afternoon constructive suggestions with respect to the bill.

I also have no doubt that the committee will give them its earnest consideration and that a better measure will result.

I do not wish to undertake an extended rebuttal of what I believe are some misconstructions of the language in the bill.

For one reason, the chairman of this gathering has by his searching questions, I believe, very frequently dissipated those misconstructions.

His evident interest in the protection of the consumer through remedial legislation, and his fairness, I am sure, will be appreciated by all those who have any connection with this measure.

I would, however, like to question whether the insertion of adverbs such as "materially", "inherently", "essentially", and the like, can be regarded as constructive suggestions by any other than members of the legal profession.

I have no doubt that they will prove a great boon to them, but I wonder whether an advertiser would feel that his interests were advanced by the ability to assert, where that his advertising was admittedly false, the defense that it was not very false, not materially false, not particularly false.

I question whether that would do him any good, and I know that it would remove teeth from the law.

I should like to present for your consideration the position which some of us who worked on the legislation find ourselves in.

In some instances we undertook the drafting of general standards of conduct. Now we find them too broad; at least, so we are told.

In some instances we endeavored to use specific statements; now we are told they are too rigid.

In some instances we sought to secure both specific rules and flexibility through the use of the administrative machinery of the Government, subject at all times to the control of our courts.

Now we are told that it is bureaucracy and tyranny.

It seems that when you put those three views together, after making proper allowance for the valuable suggestions which have come to us, the result is that there is left open only the drafting of rules which are like silent policemen at street intersections they do not cover much ground, and they are easy to get around.

I do not think that you want that sort of legislation; I am sure that the Committee does not, and yet it seems essential that in some situa-

tions there be general standards of conduct, in some situations that there be specific rules; and in some situations where specific regulations can be made under general standards of conduct which the courts can use as a guide in limiting the action of the administration, there should be the grant of administrative power.

I can assure you that this is no novelty in our law, and that its exercise would be subject to the same watchful scrutiny of the courts that any other grant of power to administrative officers is subject.

Furthermore, in almost all instances where that grant of power has been given in the bill, it has been accompanied by provision for notice and hearing.

Now, Mr. Campbell stressed the fact that at those hearings effort would be made to bring to the attention of the officer presiding, not only the Department's views, but also ample scientific testimony from whatever source available.

I think that I should make also clear that at those hearings after public notice there is and should and would be granted to the industry ample opportunity to be heard and to present its views.

There will, therefore, be the opportunity for special consideration of the special problems of industry, and there will be possible a discrimination—in the best sense of the word—in the treatment of these products.

I think that there also has been a tendency somewhat to exaggerate the extent of the granting of administrative discretion in this bill, despite the fact that no one can examine the bill without remarking its frequent appearance.

A more careful comparison of the grants of power may perhaps dispel some of those apprehensions. In many instances the grant is to accomplish a matter of form, more specifically, to set up ways of stating required information, a matter which cannot very well be put into a statute without making it resemble a tariff schedule of a tariff law.

There are also necessary grants of power to establish procedure for the conduct of the hearings, all subject, of course, to the operation of the due process clause of the United States Constitution.

I wish also to point out the fact that some of these grants of power are to exempt industries from the operation of statutory regulations where they may be harsh.

In the case of standards for food products, we have no other way of setting these standards up except as they are now established under the McNary-Mapes amendment, by administrative action. Whether you want standards or not is another thing, but I do not think that you can regard the standard-making power as an unjustified resort to administrative discretion.

The same thing, I think, can be properly be said of the voluntary inspection provision in section 22. Whether that is desirable or not, I think that the fact remains that is would be very difficult for such a system to be set up without some grant of discretionary power to the Secretary.

Certainly none of us, I suppose, would wish to see the compulsory establishment of an army of inspectors overnight, which would be necessary if there were not in the Secretary's power the power to withhold the extension of this privilege, not from specific individuals, but from classes.

In the cases of tolerances and prohibitions of adulteration of ingredients, a number of speakers have brought out the rather obvious fact that that determination is one which is dependent not only on the state of economic knowledge, but on the state of technical processes.

If, in a scientific laboratory, a wash to remove insecticides which was 100 percent effective were invented, taking a case which may seem exaggerated, the effect of such a discovery on the tolerance, of course, would be great.

It would be, in such a circumstance, unreasonable to grant the same liberality in permitting poisons to remain on a product after such a discovery as before.

In other words, here is a situation which cannot very well be handled by statute. The question is whether, after the Secretary has, following a hearing such as I described, set a standard, the industry can rely on that standard being maintained when once it has been passed upon in an appropriate action reviewing it in the courts, or whether the industry is left subject to the fate of a standard in every particular case in which it comes up, in which the Government must prove not merely the violation of the standard but the danger to health of the ingredients on the products.

With regard to the grant of administrative power as to deteriorating drug products, you have a situation in which it seems obvious, not only for the benefit of the consuming public, but also for the advantage of manufacturers to have regulations appropriately indicating when a drug would no longer be useful.

Suppose you have a case where a drug is not properly labeled with such precautionary statements, and it deteriorates. A person uses it, and injury results. Then you would have a damage suit. Is it not better to forestall a thing of that sort by an appropriate precaution in advance?

I do not believe that there have been vigorous objections made to the granting of a discretionary power there.

We could not very well include all the drugs which might be subject to such regulation without having an extended appendix to this measure, which, some have complained, is already too long to be understood, and have, in some instances, have given testimony to that accusation by their misinterpretations.

With respect to supplementing the tests to determine the quality of United States Pharmacopœia products, another grant of discretionary power, certainly there would be very few instances of its exercise, especially if the United States Pharmacopœia Convention, a national organization, keep by supplements their standards abreast of medical science.

"Permit factories", as has been explained, present a very special situation, and I think Dr. Copeland made a good suggestion by adding to the standard which was set there the words, "in such case only." The bill's standard is the protection of public health in those situations where prior inspection is the only means of detecting the wrongfulness of the product. It is an exceedingly limited section, perhaps too limited. It sets a standard which would make it easy for a producer to upset any usurpation of power by appropriate legal proceeding.

In the case of narcotics we have a possibility again of exercise of discretionary power. Dr. Beal, I think, made a very valuable suggestion in the addition of the words "habit forming" as qualifying nar-

cotics and hypnotics. It was certainly our purpose that that should be understood. But we cannot hope to anticipate, by an enumeration of drugs in a statute, the progress in the development of such products for I do not know how many years to come.

One purpose in putting in grants of administrative power in a bill of this sort is to enable the legislation to keep abreast of progress, of change in conditions, so that it will not be necessary to resort to congressional action which may itself be a burden on the industry, which may be upsetting, which certainly will be slow. On that point I should like to bring this thought to your attention:

I think there have been five amendments to the Food and Drugs Act of 1906; the last amendment which had any operation with respect to drugs was in 1912. Speaker after speaker in the last two days has brought to our attention by very candid public-spirited admissions that there are substantial shortcomings and defects in the present legislation. Now, if one quarter of the interest, one quarter of the vigor which has been expressed in opposition to this bill had been expended by the industries themselves in the support of measures in the past to remedy these defects, these hearings would not be in session this afternoon. It seems, therefore, that we cannot hope for militant action on the part of the industries to correct minor defects which is the sort of thing that the grants of discretionary power, by and large, are seeking to accomplish.

Those grants, as I say, are subject to court action. It has been desired that there be an appeal to the courts from their exercise. The regulatory power of an administrative official exercised in this fashion is not an exercise of quasi-judicial function; it is, if I may use the term, quasi-legislative. The hearings, which he would hold, are not in the nature of an adjudication of the rights and wrongs of individuals. There is no adversary party, technically, so that it seems impossible that a technical appeal could be taken. I think I can say safely that provision for an appeal from such a determination could not constitutionally be granted to the Federal District Courts of the United States. Very possibly some special tribunal might be established by statute to handle precisely such cases. However, is that necessary? That would depend, it seems to me, on the ease with which a review in the United States Federal courts might be obtained. How can that be done? In any case in which action is taken under such a regulation, its constitutionality may be questioned. It may be asserted as a defense in any prosecution based on a regulation that the regulation is unreasonable, unsupported by evidence, or without the bounds of this statute. No special proceeding has to be brought by the interested party in order to do that, or, as an alternative, he might proceed by injunction and enjoin the enforcement in advance of any wrongful administrative action. I think Mr. Campbell pointed out that at the present time there is an injunction against one of the canning standards which were set up under the McNary-Mapes amendment.

No one can very well make argument that administrative officers never blunder—that there will never be a miscarriage of justice under any legislation. We all, certainly, should be sufficiently realistic to know that it may happen; but is the reason of an occasional, and I think the record of the Food and Drug Administration indicates quite clearly that it would be only an occasional mistake of that sort, subject to review in the courts, sufficient for this group representing three important industries and their advertising media to object to this measure, which certainly has been endorsed in principle sufficiently, without a very careful examination of the risks not only to the public but to the good will which those industries now enjoy in the public eye.

Senator COPELAND. Thank you, Professor. I want to thank the many persons who have attended these hearings—thank you for the attention you have given and your courtesy and temperate speeches, and your kindly and constructive criticisms.

It has been a very interesting and highly profitable hearing. If any one of you desire to file a brief, it may be sent to the Committee on Commerce. I hope to have a meeting of the subcommittee some time before Christmas in order that amendments may be considered and bills prepared for presentation to the full committee.

STATEMENT OF W. A. HINES, OF MARLOW & HINES, ATTORNEYS AT LAW, NEW YORK CITY

Mr. HINES. The broad principles of this bill meet with general approval. No reasonable person can criticise a proposed law intended to protect the consumer against the use of poisonous materials in dangerous quantities in either foods, drugs, or cosmetics. We must register our serious objection to several provisions of the bill however, because of the ambiguity of the language used, the restrictions placed upon manufacture, sale and advertising, and the powers which it confers on the Secretary of Agriculture in enforcing its provisions. Furthermore it is vague and defective in form and its adoption would lead to uncertainty and confusion.

POINT I

REASONABLE LEGISLATION INTENDED FOR THE PROTECTION OF THE CONSUMER IS APPROVED BUT WHERE IT APPEARS THAT ONLY A TRIFLING PERCENTAGE OF A GIVEN PRODUCT IS OPEN TO CRITICISM AND THE BULK OF THAT PERCENTAGE IS MARKETED BY RACKETEERS, LEGISLATION WHICH SUBJECTS HONORABLE MANUFACTURERS TO UNREASONABLE RESTRICTIONS AND CLASSIFIES THEM WITH THE RACKETEER IS INDEFENSIBLE

The Federal Trade Commission announced recently that the toilet article and cosmetic industry in the United States does a business of $250,000,000 a year. This industry is in the main in the hands of people who do not manufacture any merchandise which would be harmful to the consumer under any reasonable circumstances. The business of these manufacturers depends entirely upon the approval of the consumer public and if the product is found to be harmful the net result is that the manufacturer loses his consumer and his business suffers to precisely that extent. There are, it is true, a small number of racketeering manufacturers throughout the country who indulge in all forms of misleading and inaccurate advertising, who make absurd claims as to curative and other properties for their product, and who manufacture merchandise which they must know to be harmful and even dangerous. There are but a few of this type, however, and their methods are such that they cannot be controlled, not to say eliminated,

except by penal statutes. We submit, however, that a bill such as S. 1944 in its present form classifies the honest manufacturer with the criminal and, even further, places him in a position where he must prove his innocence or go out of business.

No consumer or group of consumers would welcome legislation which would eliminate the racketeer more than the legitimate manufacturer of cosmetics. The consumer, after all, is the foundation stone of every prosperous business. If the manufactured article is harmful, the manufacturer loses not one but thousands of present and prospective customers. It probably never occurred to the women representatives of consumers' organizations who testified before this committee in support of the bill on December 7 that there was anything to discuss but the unfortunate results of the experiences symbolized in the so-called "Chamber of Horrors" which had been so cleverly built up and dramatically displayed in 26 exhibits throughout the country by the Department of Agriculture as propaganda in support of the bill. We know of nothing more contemptible than this method of influencing public opinion, unless it be the use of the radio by agents of the Department to deliberately convey to millions of homes the thought that the Department had investigated, and as a result of its investigation had condemned the entire industry; the implication being that if the bill is enacted into law the Department itself will "run" the business and the millenium will have arrived. An entire nation may not be indicted, and this is equally true of an entire industry. We resent the imputation that our business is dishonest; that our product is made in any part of harmful materials; that anything is used in the articles we manufacture which is not on a par with the highest standards—even higher than anything the Department now prescribes. We are willing to go further: If at any time, because of developments in the field of chemistry having to do with the public health or for any other good and sufficient reason, any responsible Department of the Government suggests a reasonable change in the components of or the methods of manufacture of any of our products, we will promptly comply with the suggestion. We will not demand a formal order from the Department. We will not put the Government to the trouble of moving for an injunction. In the light of our willingness to cooperate with the Government in the interest of public health, we respectfully submit that there is no occasion for legislation which would result in placing Government agents in our factory, stifle our legitimate and truthful advertising, and practically place the control of our affairs in a Department of the Government.

Several of the provisions of the bill are so unreasonable that they seriously hamper the legitimate manufacturer in the conduct of his business and we maintain that under these circumstances, the bill is indefensible regardless of the motive behind it.

Point II

OUR FORMULAE ARE PROPERTY RIGHTS. IF WE ARE REQUIRED TO DIVULGE THEM TO AN AGENCY OF THE GOVERNMENT OR TO PUBLISH THEM BROADCAST BY ANY MEDIUM, IMITATIONS OF OUR PRODUCTS MADE OF INFERIOR MATERIALS AND SOLD UNDER A NAME SIMULATING OUR REGISTERED NAME WILL BE MARKETED BY RACKETEERS, SOLD AT A LOWER PRICE AND CAUSE US SERIOUS LOSSES.

There seems to be no doubt that the real purpose of the framers of the bill is to vest arbitrary and dictatorial powers in the hands of the Secretary of Agriculture. Fears have been repeatedly expressed and the statement has been made in one or more of the radio broadcasts by agents of the Department of Agriculture that one of the purposes of the bill is to require that the label covering cosmetics shall set forth the formula of the contents of the package. This, if true, would be absolutely destructive of the property rights of legitimate manufacturers in the duly registered names of their products. If this requirement becomes the law, it would be but a matter of a very short time before the racketeering manufacturer would be simulating such registered products, using inferior ingredients and marketing his product at a comparatively small price under a name sufficiently similar to the original to deceive the consumer public. If and when this state of affairs comes about, the legitimate manufacturer may just as well go out of business. The proposed law would then be playing into the hands of the very class responsible for the conditions which have brought about the fanatical attempt at reform which the bill symbolizes.

The Government may at any time analyze any of our products. We do not manufacture any product containing harmful or poisonous materials. At any time after such analysis of any merchandise made by us, if and when it is found to contain any substance which the Government believes to be harmful, we will discontinue its manufacture.

It is respectfully submitted, however, that requiring us to make formulae of our products a matter of public knowledge, formulae which are unquestionably a property right, and particularly in the absence of any attack on the purity of our merchandise by a Federal department, is a dangerous proceeding and destructive to our property interests. When and if the Government can show that any merchandise produced by any manufacturer contains deleterious or poisonous substances, a provision in the bill for a cease-and-desist order along the lines of the Federal Trade Commission Act would give ample power to the Government to enforce its findings. The proposed bill, however, takes the opposite course and in effect places the burden on the manufacturer of proving his innocence. It is therefore much worse than a penal statute.

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Point III

ILLUSTRATIVE OF THE PREVAILING TENOR OF THE BILL, SECTIONS 12 AND 13 PROPOSE IN EFFECT THAT THE GOVERNMENT TAKE OVER AND RUN THE ENTIRE INDUSTRY AS A FEDERAL HEALTH MEASURE

Under section 12 (a), (b), (c), and section 13 (a) of the proposed bill, the Secretary of Agriculture is vested with power to make regulations covering the conditions of manufacture, processing, and packing as he deems necessary to protect the public health and requiring manufacturers to hold permits for such manufacture, etc. These provisions obviously mean that all manufacturers of cosmetics, good as well as bad, shall be subjected to constant supervision by Government agents. Section 12 (a) is as follows:

SEC. 12. (a) Whenever the Secretary finds that the distribution in interstate commerce of any class of food, drugs, or cosmetics may, by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health, and such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he is authorized, after notice and hearing, to make such regulations governing the conditions of manufacture, processing, or packing as he deems necessary to protect the public health, and requiring manufacturers, processors, and packers of such class of articles to hold a permit conditioned on compliance with such regulations.

This provision is susceptible of only one construction. It simply means that if manufacturer A makes a cold cream under the conditions which this subdivision recites, that manufacturer B, C, etc., who make the same *class* of merchandise under absolutely healthful conditions, will nevertheless be required to hold a permit issued by the Secretary quite the same as manufacturer A.

This subdivision is in absolute harmony with the spirit of the entire bill. It means that the honest manufacturer is to be punished for something the racketeer has done. The proposed remedy is so obviously unfair and unreasonable that it is indefensible.

Point IV

CONCLUSION AND RECOMMENDATIONS

We have indicated under Point II that anything in the bill requiring us to disclose the formulae of our products in any manner whatever would amount to a deprivation of our property rights and we submit that, in view of the many ambiguities of the bill, an express provision should be incorporated therein to clearly dispose of this question. For this purpose, we suggest a paragraph in the appropriate place as follows:

Nothing in this Act shall be construed as requiring that manufacturers of cosmetics shall disclose the formulae of their products, either on the labels of the container or elsewhere or to any officer of the government.

As it is our desire to assist the committee in charge of the bill as much as possible in its revision, we respectfully submit the following further suggestions as to the various sections of the bill relating in whole or in part to cosmetics, which in our opinion and for the reasons set forth herein should be amended before the subcommittee makes its report. In the first column we show the section in which we are interested and in the second column the amendment which we suggest.

SECTION 6 (a)

If its labeling is in any particular false or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetic.	If its labeling is in any material particular false or ambiguous. (NOTE.—Inferences and misleading impressions on the consumer are too nebulous for serious consideration.)

SECTION 9 (a)

An advertisement of a food, drug or cosmetic shall be deemed to be false if in any particular it is untrue, or by ambiguity or inference creates a misleading impression regarding such food, drug, or cosmetic.	An advertisement of a food, drug or cosmetic shall be deemed to be false if in any material particular it is untrue. (NOTE.—Inferences and misleading impressions on the consumer are too nebulous for serious consideration.)

SECTION 10 (a)

If the Secretary finds that the presence of an added poisonous or added deleterious substance in or on food or cosmetics is or may be injurious to health, taking into account other ways in which the consumer or user may partake of or be exposed to the same or other poisonous or deleterious substances, then the Secretary shall by regulations promulgated after notice and hearing prohibit such added substances in or on food or cosmetics, or establish tolerances limiting the amount therein or thereon, to such extent as he may deem necessary to prevent such injury to health.	If the Secretary finds that the presence of an added poisonous or added deleterious substance in or on food or cosmetics is injurious to health, then the Secretary shall by regulations promulgated after notice and hearing prohibit such added substances in or on food or cosmetics or establish tolerances limiting the amount therein or thereon, to such extent as he may deem necessary to prevent such injury to health. (NOTE.—The phrase "taking into account other ways in which the consumer or user may partake of or be exposed to the same or other poisonous or deleterious substances" opens the door to contingencies which no legislation should or could provide for; circumstances for which the manufacturer should not be held responsible, such for example, as mistaking one tube for another in a drug cabinet.)

SECTION 12 (a) (b) (c) AND SECTION 13 (a) (b)

These sections should be stricken from the bill and substituted by appropriate provisions giving the Secretary of Agriculture reasonable power under a finding that any of the acts provided in the said sections are injurious to the public health, to serve a cease and desist order on the manufacturer; if such cease and desist order is not obeyed, to move for an injunction in a Federal court against such manufacturer.

SECTION 16 (a)

Approved subject to the excision of the following words in lines 16, 17, 18, 19: "The operator of which did not, at the time of manufacture, processing, or packing hold a valid permit if so required by regulations under section 12,"

(NOTE.—We have recommended that section 12 be stricken from the bill.)

SECTION 16 (d)

Approved subject to the excision of the following words on lines 20, 21, 22, 23: "Any article condemned by reason of the manufacturer, processor, or packer not holding a valid permit when so required by regulations under section 12 shall be disposed of by destruction."

(NOTE.—We have recommended that section 12 be stricken from the bill.)

SECTION 17 (a) (5)

Should be stricken from the bill.

(NOTE.—We have recommended section 12, herein referred to, should be stricken from the bill.)

SECTION 17 (6) (b)

Approved, allowing for the excision of (5) above.

SECTION 17 (d)

This subdivision should be stricken from the bill as it merely releases one class of offenders from prosecution and inferentially places the guilt on another. The guilt of the informer or the other party to the contract or both is a matter for a jury to pass upon. No publisher, etc., should be exempted from prosecution merely by alleging that the other party was the offender.

SECTION 17 (e)

This subdivision should be stricken from the bill for the reasons mentioned above.

SECTION 17 (f)

Approved except that the word "Sections" on line 16 be changed to the singular, to wit, "Section", and the excision of the numeral "12" and the word "and" immediately following on line 16.

(NOTE.—We have recommended that section 12 be stricken from the bill.)

SECTION 18 (a)

This subdivision should be stricken from the bill. It is purely a question for a jury.

SECTION 18 (b)

This subdivision should be stricken from the bill. It is purely a question for a jury.

SECTION 21

This section is approved but with a condition that the final determination of all judgments, degrees, orders, proceedings instituted, and seizures made, or the abandonment or reversal of such judgments, decrees, orders, proceedings instituted, and seizures made shall likewise be published by the Secretary.

SECTION 24

This section should be stricken from the bill on the ground that it is unnecessary. A common-law right of action exists.

STATEMENT OF J. A. LADDS, FIRST VICE PRESIDENT OF THE ALLIED MANUFACTURERS OF THE BEAUTY AND BARBER INDUSTRY, INC.

Mr. LADDS. This organization, I may explain, is a trade association of manufacturers of cosmetics, mechanical equipment, permanent wave machines and supplies, hair dyes, hair rinses, and kindred items particularly adapted for use in the beauty and barber shop field. The association is, therefore, especially interested in any legislation affecting the manufacture and control of cosmetics by the Federal Government.

The association has given very careful consideration to the legislation now proposed, had representatives at the hearings of your committee in Washington, and is disposed to cooperate in every possible way in the matter of securing the enactment of reasonable and proper legislation to meet the general purposes in view. The

association feels, however, that the proposed measure is, in its present form, impractical and unworkable and places in the hands of a Government official vast powers capable of grave abuse. With this situation in mind, I wish to bring to the committee's attention certain suggestions by way of amendment, which, it is believed, will be of a constructive nature.

The following amendments are accordingly respectfully submitted:

I

Proposed amendment: *Section 5 (a)*: On line 14, page 6, in place of the language "if it is or may be injurious to the user * * *" substitute the following: "if it is dangerous to public health * * *"

Comment: The definition of adulteration of cosmetics, as contained in the present draft of the act, makes no allowance for the possible idiosyncrasy or supersensitiveness of the user of a cosmetic. Almost any cosmetic may in rare instances result in irritation to a user who is supersensitive to some of its ingredients. Under the present working of the act, if a corporation ships in interstate commerce a cosmetic which to the overwhelming number of users is harmless, but which is a negligible number of cases may cause irritation, real or fancied, on account of some supersensitiveness, idiosyncrasy, or pathological condition, its officers may be prosecuted, fined, or imprisoned. The change in language proposed above, it is relieved, would assure to the Secretary of Agriculture and to the courts a reasonable latitude in the application of the law to products of this class which, on the one hand, could not be said to countenance general and arbitrary prohibitions, and, on the other hand, would permit effective and adequate protection to the public.

II

Proposed amendment: *Section 6 (b)*: On line 3, page 7, after (2) add the words "in the case of foods and drugs." On lines 8 and 9 of page 7, omit the words "and cosmetics."

Comment: So far as cosmetics are concerned, the provisions of 6 (b) (2) are burdensome and unnecessary. Consumers do not buy cosmetics by weight. They buy the brand they desire and willingly pay the price for that brand. In view of the fact that weight is not an important element in the mind of the purchaser, it would appear unnecessary to impose upon the manufacturer the burdens which this provision would entail. It is not easy to standardize the exact weight or the exact volume of the contents of cosmetic containers, and any attempt to do so would result in annoyance and expense totally out of proportion to any benefit conferred upon the purchaser. As to the effect or desirability of this subdivision with respect to food and drugs, no comment is made since the representatives of the food and drug industries are obviously best qualified to speak on this point.

III

Proposed amendment: *Section 8 (e) (2)*: Lines 3–5, page 11, strike out the following language after the word "be": "and (2) the name and quantity or proportion of each medicinal or physiologically active ingredient thereof." Line 8, page 11, add after the word "health" the following: "provided that nothing herein contained shall require the disclosure of any formula."

Comment: See comment under proposed amendment V infra.

IV

Proposed amendment: *Section 10 (a)*: On lines 24 and 25, page 14, and line 1, page 15, in place of the language "is or may be injurious to health, taking into account other ways in which the consumer or user may partake of or be exposed to * * *" substitute the following language: "is dangerous to the public health, taking into account other ways in which the consumer or user has under normal conditions partaken of or been exposed to * * *."

Comment: This suggestion is prompted by the same considerations set forth in the comment with respect to the amendment proposed above to section 5 (a).

V

Proposed amendment: *Section 13* (*a*) (*2*): On lines 22–23, page 17, strike out the words "methods, processes". On line 23, page 17, strike out the words "and unfinished".

Section 13 (*a*) (*2*): On line 24, page 17, add the following proviso: "provided that nothing herein contained shall require any manufacturer to disclose any method, process, or formula".

Section 13 (*b*) (*1*): On line 10, page 18, also strike out the words "methods, processes" and "and unfinished".

Comment: The above change is suggested in order to insure the protection of valuable formulae and methods and processes of manufacture. The formulae and methods and processes of manufacturing cosmetics are property rights recognized as such by the courts, and frequently are of enormous financial value. The acquisition of such information by competitors would in many instances spell ruin of an established business. Under the section as drawn, Government inspectors would have access to all such secrets. While publicity to such secrets is doubtless not contemplated, it would be a practical impossibility to protect the manufacturer under such circumstances against the risks of such valuable information getting into the hands of actual or potential competitors.

VI

Proposed amendment: *Section 15:* On page 20 add paragraph (d) to read as follows: "Excepting in cases threatening grave and imminent danger to the public health, the Secretary shall, before instituting any civil action authorized by this Act, afford due notice and opportunity for hearing to interested parties in accordance with such regulations as the Secretary shall prescribe."

Comment: The above provision is recommended in order to afford and assure manufacturers opportunity for administrative relief in all ordinary cases and to avoid insofar as possible the danger and embarrassment, to an innocent manufacturer, of public court action without notice.

VII

Proposed amendment: *Section 16* (*a*) (*2*): On lines 2 and 3, page 21, in place of the language "imminently dangerous to health * * *" substitute the following language: "Imminently dangerous to the public health * * *".

Comment: This suggestion is prompted by the same considerations set forth in the comment with respect to the amendment proposed above to section 5 (a).

VIII

Proposed amendment: *Section 21:* Lines 22–25, page 28, and lines 1–3, page 29. Strike out the language following "* * * and orders which have been rendered,".

Comment: The powers contained in the language struck out are capable of grave abuse. The Secretary of Agriculture, it is submitted, should not be enabled to disseminate statements adverse to the interests of a manufacturer until the manufacturer has had his day in court and has been adjudicated guilty.

IX

Proposed amendment: *Section 22:* Strike out this section in toto.

Comment: The service provided in this section, while stated to be a "voluntary inspection service", is, in effect, a compulsory inspection service. If one manufacturer avails himself of the service, every manufacturer will, as a practical matter, be required to in order to avoid being placed in an unfair competitive situation. It is not the business of the Government to make what are in effect recommendations as to particular products. Furthermore, the transfer to the manufacturer of the expense of maintaining the army of inspectors, which would be required under this section, would effect by indirection the imposition of a heavy additional tax.

X

Proposed amendment: *Section 23* (*c*): Substitute for the paragraph in its present form the following: "Regulations relating to adulteration, misbranding, false advertisement, and tolerance, as authorized in sections 3–10, inclusive, of this act, shall be prescribed upon the joint authority of the Secretary of the Treasury, the Secretary of Agriculture and the Secretary of Commerce. Regulations relating to imports, as authorized in section 20 of this act, shall be prescribed upon the joint authority of the Secretary of the Treasury and the Secretary of Agriculture. The Secretary of Agriculture is authorized to prescribe such further regulations as may be necessary and appropriate to the efficient enforcement of the functions otherwise vested in him by the provisions of this act, including regulations with the force and effect of law as to notice and conduct of hearings by the Secretary of Agriculture."

Comment: In the hearings on this bill neither Secretary Wallace nor Mr. Campbell called attention to the fact that, while the proposed legislation would vest practically all regulatory authority in the Secretary of Agriculture, the existing Food and Drugs Act (section 3) provides that all rules and regulations must be prescribed by "the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce." The vital interests of the Treasury Department in the Food and Drugs Administration through its Bureau of Public Health Service and of the Commerce Department through its Bureau of Foreign and Domestic Commerce and its Bureau of Standards are too apparent to justify their participation of the Food and Drugs Administration being terminated without most serious consideration of the reasons involved. Since the proposed legislation contemplates a much greater delegation of legislative control over the food and drug industries and the inclusion of the cosmetic industry as well, the more reason exists in the interest of fair administration for not accompanying this added delegation of control with a complete concentration of authority in the Secretary of Agriculture. Industry, it is believed, could look forward to the new control with much greater confidence and assurance of fair treatment if the Department of Commerce had a voice in formulating the most important regulations.

XI

Proposed amendment: *Section 23* (*c*): This paragraph, by providing that "the findings of fact by the Secretary shall be conclusive if in accordance with law" in all hearings authorized or required by this act, would effect a delegation of judicial authority, which, when added to the wide administrative and enforcement powers elsewhere conferred, would make the Secretary of Agriculture a practical dictator over the food, drug, and cosmetics industries of the country. In view of the enormous business and public interests involved and the broad powers of regulation in contemplation, it would seem that the matter is of sufficient importance, in order to avoid abuse of authority and to assure fair treatment to all concerned, to warrant the creation of an independent board or commission comparable to the Board of Tax Appeals or the Federal Radio Commission, as the final administrative and fact-finding tribunal. In the absence of such independent board or commission it is submitted that the rulings of the Secretary of Agriculture or his agents should by definite and specific provisions be made subject to court review. In this connection attention is invited to the right of appeal from the findings of the Commissioner reserved to manufacturers under "the National Prohibition Act", section 5 of this act providing as follows:

"The manufacturer may by appropriate proceeding in a court of equity have the action of the commissioner reviewed, and the court may affirm, modify, or reverse the finding of the commissioner as the facts and law of the case may warrant and during the pendency of such proceedings may restrain the manufacture, sale, or other disposition of such article." (41 Stat. 305.)

XII

Proposed amendment. *Section 24.*—Strike out this section in toto.

Comment: This act should not attempt to modify or restate the common law with respect to personal injuries.

A copy of Senate Bill 1944, in which the proposed changes or amendments have either been pasted or typed in, is enclosed herewith for convenience.

We suggest the following amendments:

On page 6, line 14, strike out the words "or may be injurious to the user" and insert "dangerous to the public health".

On page 7, line 3, after the figure (2), insert the words "in the case of food and drugs".

On page 7, strike out the last word in line 8 and the first word in line 9.

On page 11, line 3, put a period after the word "be" and strike out the remaining words in the line.

On page 11, strike out all of line 4.

On page 11, line 5, strike out the words "active ingredient thereof."

On page 11, line 8, change the period after the word "health" to a colon, and add the following: "Provided, that nothing herein contained shall require the disclosure of any formula."

On page 14, line 24, strike out the words "or may be injurious to" and insert the words "dangerous to the public".

On page 14, line 25, strike out the last word in the line and insert "has under".

On page 15, line 1, strike out the words "partake of or be" and insert the words "normal conditions partaken of or been".

On page 17, line 22, strike out the following "methods, proc-".

On page 17, line 23, strike out "esses,".

On page 17, line 23, strike out the words "and unfinished".

On page 17, line 24, after the word "stored", change the period to a colon, and add "Provided, that nothing herein contained shall require any manufacturer to disclose any method, process or formula."

On page 18, line 10, strike out the words and figures "methods, processes," and also the last two words in the line "and unfinished".

On page 20, between lines 11 and 12, add a new paragraph as follows: "(d) Excepting in cases threatening grave and imminent danger to the public health, the Secretary shall, before instituting any civil action authorized by this Act, afford due notice and opportunity for hearing to interested parties in accordance with such regulations as the Secretary shall prescribe."

On page 21, line 3, between the words "to" and "health", insert the words "the public."

On page 28, line 22, change the comma after the word "rendered" to a period, and strike out everything that appears thereafter on the page.

On page 29, strike out everything appearing thereon.

On page 30, strike out lines 1 and 2.

On page 30, strike out from lines 4 to 17, inclusive, and insert in its stead the following: "Sec. 23 (a). Regulations relating to adulteration, misbranding, false advertisement, and tolerance, as authorized in sections 3–10, inclusive of this act, shall be prescribed upon the joint authority of the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce. Regulations relating to imports, as authorized in section 20 of this act, shall be prescribed upon the joint authority of the Secretary of the Treasury and the Secretary of Agriculture. The Secretary of Agriculture is authorized to prescribe such further regulations as may be necessary and appropriate to the efficient enforcement of the functions otherwise vested in him by the provisions of this act, including regulations with force and effect of law as to notice and conduct of hearings by the Secretary of Agriculture."

On page 31, strike out lines 5, 6, 7, and 8.

RESOLUTION OF SOROSIS CLUB OF CLEVELAND, OHIO

CLEVELAND, OHIO,
December 19, 1933.

Hon. ROBERT CROSSER,
House Office Building, Washington, D.C.

DEAR SIR: The Cleveland Sorosis Club, an organization of nearly 175 members, endorses the Federal Food and Drugs Act, Bill S-1944 and asks that you support it.

We would appreciate having our resolution included in the official record of the hearing on the bill.

Very sincerely yours,

(MRS. LEWIS) FLORABELL WINTERMUTE,
Corresponding Secretary.

17601 WINSLOW ROAD, *Shaker Heights, Ohio.*

STATEMENT OF MARCUS KASAN, OF THE KASAN, ANDERSON & KASAN, ATTORNEYS FOR THE CHICAGO PROPRIETARY PACKAGE MEDICINE ASSOCIATION

Mr. KASAN. A thorough consideration and investigation of the Food and Drugs Act of June 30, 1906, and its amendments thereto, wherein "Regulation 1 gives the title of the act as an act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for the regulating traffic therein, and for other purposes", proper interpretation of these words covers every conceivable form of violation and for the purposes of authority leave no additional powers that can be properly granted to the administrators of the act.

Regulation 2: Scope of the act: The provisions of the act apply to foods and to drugs which have been shipped or delivered for shipment in interstate commerce or which are exported or offered for export to foreign countries, it will readily be seen from this provision that the scope of the act is unlimited.

Regulation 3: Collection of samples and evidence for action under sections 1, 2, and 10. Section 3 of same provides a sample for examination by or under the direction and supervision of the Food and Drug Administration shall be collected by an authorized agent of the Department of Agriculture and in a subsequent amendment it is also provided for seizure of any article in transit that may be of a questionable nature.

Regulation 4 provides for a method of analysis of the seizure.

Regulation 5 provides for hearings and trial and criminal prosecution. Paragraph c of regulation 5.

Regulation 8 provides for standards for drugs.

Regulation 14: Label, section 8, paragraph a, the term "label", as used in the act, includes any legend and descriptive matter or design appearing upon the article or its container, and also includes circulars, pamphlets, and the like which are packed and go with the article to the purchaser, and such letters, circulars, and pamphlets to which reference is made either on the label attached to the package or on the package itself; the most perfunctory glance at this section demonstrates a profound insight into the practical end of the patent medicine business formidable and complete in every detail, a thing conspicuous by its absence in the proposed Tugwell bill.

Regulation 23 provides certain adulterations not corrected by label, section 7, proper labeling alone will not remove an article from the operation of the law. Certain forms of adulteration, e.g., the addition of a poisonous or deleterious ingredient which may render the article injurious to health, cannot be corrected by any form of labeling. This section demonstrates the wide scope of this act.

Regulation 24: Substances required to be stated on the label.

Regulation 25: Method of stating quantity or proportion.

Regulation 26: Statement of weight, measure, or count.

Regulation 27 provides for articles intended for export.

Regulation 31 provides for alterations and amendments of regulations. These regulations may be altered or amended at any time without previous notice, with the concurrence of the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce. The foregoing rules and regulations are hereby adopted, effective on this date, and all previous regulations for the enforcement of the Federal Food and Drug Act are hereby rescinded.

A. W. MELLON,
Secretary of the Treasury.
ARTHUR M. HYDE,
Secretary of Agriculture.
R. P. LAMONT,
Secretary of Commerce.

WASHINGTON, D.C., *October 31, 1930.*

From the foregoing it is evident to anyone that cares to read and who has some knowledge of law and of the modus operandi of the Department of Agriculture in its handling of these matters that within their hands rest the civil life of the manufacturer or seller, via analysis after purchase or seizure of the questioned article, trial, finding, and postal fraud order which if put into execution obliterates the manufacturer or seller as though he never existed supra regulation 3.

Regulation 5 provides for criminal prosecution of the one charged with an offense against these laws,with a punishment running as high as 1 year imprisonment and a $1,000 fine, which if analyzed means that in lieu of the defendant possessing the necessary $1,000 he may be compelled also to serve 4 years in prison.

These punishments seem to us severe enough to even satisfy a lust for blood should one be so fastidious in his just indignation; these remedies which include the high prerogative writ of extra-judicial injunction, i.e. the fraud order stopping all business relations with the world at large with imprisonment added, make it seem to us like the execution of a man plus a 10-year sentence at hard labor and in our humble opinion legal verbiage inflicting any additional tortures for purposes of making one more ethical are almost impossible of conception; insofar as punishment is concerned the proposed bill has added nothing to it.

The same is true of the regulations heretofore prescribed with reference to the conduct of the business; its language cannot be more severe or direct or demanding of a higher code of ethics in any business.

In contradistinction to the intriguing and mysterious title given the proposed bill, whose ramifications under section 1, title 1, in its finish "and for other purposes" transcends all of the realms of fable and mystery.

Plus section 2 (j). Whose definition of the term advertisement (includes all representations of fact or opinion disseminated in any manner or by any means other than by the labeling) surely reaches the ethereal and lacks every compliment to the intelligence of the American public and Congress, its palpable vagueness being so patent that the proponent of this bill must justly be deemed to be a deep student and reverencer of the late Barnum and Bailey and its definition of humanity.

Another literary gem is section 3 of the proposed act, which provides as follows: Adulteration of food. A food shall be deemed adulterated (a) (1) if it is or may be dangerous to health. Also section 4 (a) similarly relating to adulteration of drugs. Also section 5 (a) similarly relating to adulteration of cosmetics, and by the wide spaces for interpretation left in same demonstrates to the unwary and

uninitiated how careful they should be before they sign on the dotted line.

The foregoing three comments on the life's-blood definitions in the bill proposed will hardly be seriously questioned by the makers and best friends of same, and for the purposes of review we shall conclude with this statement: We represent a group of proprietary package medicine firms who directly and indirectly employ some 3,000 people at the present time. This number has but lately been reached; to within 4 or 5 months ago it did not exceed 500, and it is their voice that I am asking you to listen to. We can only guess at the motive of the bill in question that is contemplated, from exhibit 1 hereto attached known as the "Tabloid News", November 24, 1933, volume 1—issue no. 8, a publication that has but recently come to life and which seems to be working with the American Medical Association and a subsidiary named the Consumers Research League, Inc., of Washington, N.J., wherein the family of the President of the United States, Mrs. Franklin D. Roosevelt and Mrs. Anna Dall, are drawn into this controversy on behalf of the American Medical Association and the various doctors espousing this bill, and there is great capital made in this issue of the fact that an excessive price was paid for a cure for diabetes, same having been exhibited to the astonished ladies aforesaid at Dr. Tugwell's showing at his chamber of horrors, wherein they also exhibited death certificates of the users of these remedies; the expounder of this article, which is headed Rout the Medicine Makers!, failed to add that the ladies in question, if they had been more perceptive than horrified and had looked at the death certificates and noted the ages upon them, they would have found that the users of these remedies, instead of dying from diabetes, die from old age.

The above-exhibited at the World's Fair, plus the public platform, the radio, the newspaper, and the all-powerful moving picture, as propaganda for the passage of this act, makes one doubt the merits of this bill, of its sincerity, as in human experience a thing that is reasonable will stand of its own weight, without all of these supporting columns and crutches advanced for this bill, and makes it seem as though the medical profession were heavily affected by the late depression and in their just energy and ambition were seeking a new source of revenue by compelling people to resort to them for prescriptions, purchases of medicine, and medical treatment in the most trivial matters. This would of course be very good for the doctors but a trifle exacting upon the said John Public, whom the proponents of this bill are with such vim and vigor protecting and saving from disintegration.

And by its context renders it liable at the hands of persons who are not so charitably inclined to be the recipient of that undesirable public comment so colloquially used in this modern age and termed "a racket", which has been known to conclude many public careers and measures and, of course, it is but right to assume that everyone connected with this measure desires to give no room for such reference.

Therefore in keeping with out first comment that we represent close to 3,000 people of the common strata of life, just the average workman and his family that are holding jobs at the present time, we know they do not rate very high in a social scale, but we also feel that they are here and once born have the same right any other person has under the Constitution; they are not here because they sought

to come here and they will go without wanting to go when the time comes; we cannot order them executed because they are too many, and we have no sterilization act that may perform that function for us, therefore, we must provide a living for them and they have the right to the enjoyment of an honest day's work for a fair day's pay; they want no dole, these people whom we represent tasted the bitter bread of charity all of last winter, it did not go over so big. The experience of an able-bodied man walking the streets with a family at home without food and without food himself, with no money in his pocket and in reality not a place to sleep, are such as, I am sure, the gentlemen of this committee are unacquainted with, but the endurance and the suffering of the people engaged in the trade on whose behalf this brief is filed are beseeching you gentlemen not to hurl them back into the street by the passage of your mysterious bill, as the old act is more than sufficient to cover everything that you propose in your new act and the people in whose behalf we speak are but a very small part of the mass involved in this legislation, and the day you pass this Tugwell bill giving dictatorial power wholly unnecessary and un-American to the Secretary of Agriculture to destroy any patent-medicine firm in America, you want to be sure, as an act of courtesy, that you also attach a rider to said bill providing a reasonable upkeep per week for close to half a million people, as that many would be affected directly or indirectly and they would have every right in the world to look to the Government that enacted this bill, to provide something suitable in the way of a livelihood to take the place of their present means of sustenance.

Rout the Medicine Makers

[The Tabloid, Philadelphia, Pa., Nov. 24, 1933]

Dispatches from the Nation's capital indicate that no less a personage than Mrs. Franklin D. Roosevelt has interested herself in the drive to make advertising untruths illegal.

Assistant Secretary of Agriculture Rex Tugwell, author of the proposed Tugwell bill, which will be presented to the next Congress as a means of providing Federal control over advertising of food, drug, and cosmetic products, is declared by George Durno, International News Service correspondent at Washington, to have enlisted the aid of Mrs. Roosevelt and her daughter, Mrs. Anna Dall, in his campaign.

The First Lady and Mrs. Dall motored to the Agricultural Building wherein Tugwell has set up his "chamber of horrors." They were astonished at the significant display. They viewed with alarm the "cure" for diabetes, which sells for $12 a pint. Alongside the carton containing the nostrum they saw a group of testimonials from persons reputedly cured by the faked "cure."

And on the other side they saw the death certificates of the same persons. They also saw the picture of a truly beautiful woman who ranked high socially in a Midwestern town. Later, they saw a horrible photograph of her sightless eyes—the result of having her eyelashes dyed with a certain preparation in anticipation of attending a testimonial banquet her grateful clubwomen were tendering. That particular preparation was exposed as a fraud in a recent issue of the Tabloid.

Mrs. Dall will comment on the startling exhibition in her Liberty Magazine column. Mrs. Roosevelt vowed she would lecture on the subject. Both ladies were honestly horrified.

And well they might be.

The United Medicine Manufacturers of America, in their recent Chicago convention, drew up imposing regulations condemning the proposed Tugwell bill, outlining 17 specific points to which they objected.

With their battle cry calling attention to the "inalienable right to self medication" being sounded, the organization drew plans for a concerted drive to nullify the Tugwell bill. Extensive propaganda, a lobby on Congress, and the enlistment of allied industries will be used to defeat the proposed law.

The medicine makers must not succeed.

The Food and Drug Administration, whose powers would be greatly increased under the Tugwell bill, answer the medicine makers' complaints with the single argument: "Is the right to self medication denied by requiring that drugs be labeled with directions for use under which they will not be dangerous to health? Or requiring that drugs actually possess the remedial value ascribed to them in their labeling?

"Will the right of the consumer to medicate himself be abrogated by requiring the identity of drugs to be revealed on the label, so he can have full knowledge of what he is getting and whether it is habit forming?"

The answer to these questions is, of course, no.

Fake Shampoo Sells For $1.05 Bottle But is Only Salt Water

BY HARVEY LEROY

Mix together 5 ounces of water, a pinch of salt, and a couple drops of perfume and what have you?

A preparation worth nothing? No, kind reader, you have a bottle of "Oyloff Dry Shampoo." And you'll pay $1.05 for it, too. At least that is the contention of the makers of this nostrum, who advertise the water-salt-perfume mixture as the finest shampoo on the market.

The Godefroy Manufacturing Co., of St. Louis, who make "Oyloff Dry Shampoo" did a rushing business until the American Medical Association got wise to them.

The manufacturers were not a bit bashful in their unusual claims for their salt and water product as is evidenced by the article in the Journal of the American Medical Association. The article quotes an advertisement which appeared in the Ladies' Home Journal, as follows:

"Amazing new liquid makes shampooing quick, easy, right at your dressing table.

"Here is what you have always wanted, a thrilling new way to shampoo your hair in 15 minutes without washing out your wave."

The A.M.A. purchased a bottle of the stuff to find out what it contained. (Article doesn't say whether or not the Medical Association was thrilled.)

The cost of the bottle was $1.05, the liquid coming "in a most modernistic container, characteristically of the present high-hat tendency in the cosmetic trade."

The chemical laboratory of the A.M.A. analyzed the preparation and announced that—

"Qualitative tests indicated the presence of sodium and chloride. No heavy metals, carbonates, sulphates, alkaloids, and soap were found. The specific gravity, etc. * * *

"From the foregoing tests it was concluded that Oyloff is essentially a colored solution of dairy salt (commercial table salt) with a dash of perfume."

The A.M.A. article continues:

"From the chemists' report we learn that this 'amazing' product that reveals the 'romance of your hair' and that will 'thrill you' is, essentially a pinch of salt in 5 ounces of water—incidentally the bottle states 'net contents, 6 ounces.' Paying $1.05 for 5 ounces of salt water would seem, under present economic conditions, to furnish a text for a discussion on certain phases of modern business."

National Sanipractic Association,
Seattle, Wash., December 2, 1933.

Senator Homer T. Bone,
Washington, D.C.

Honorable Sir: Nearly 1,500 people, incensed at the autocratic attempt of the American Medical Association, in reality the biggest trust in America, to become dictator in health matters through Rexford G. Tugwell and his so-called food, drug, and cosmetic bill, gathered at the Masonic Temple here Friday evening to give voice to their objections.

The objections to the bill are that:

It is altogether too sweeping, and the powers given the Assistant Secretary of Agriculture are dictatorial in that there is no recourse to the courts;

The "Secretary's" opinion is to be based upon medical opinion, and this means the American Medical Association, which in practice would discriminate against all other systems of healing;

The term "drug" as defined in sec. 2 (B) is so inclusive as to take in anything and everything that they might choose to include in their textbooks; thereby they would gain supreme power.

The bill should be indefinitely postponed, as it is a clever method whereby the American Medical Association can later sweep through the State legislatures, gaining similar State authority by which they could wipe out the new schools of healing. The amendment which we enclose with this letter should be included if it is likely to pass.

We wish to also call your attention to the enclosed printed matter, especially the brochure upon which the American flag is printed. The magazine, Sanipractic, tells of the medical freedom meeting spoken of in this letter.

Respectfully yours,

NATIONAL SANIPRACTIC ASSOCIATION, INC.
By JOHN E. LYDON, *President*.

S. 1944 (OR TUGWELL BILL)

Amend section 2, subdivision (B) in line 11, after the word "Animals", insert: "*Provided*, This Act, shall not affect the practice of sanipractic, or osteopathic physicians, or doctors of chiropractic, food science, mechano-therapy, psychotherapy, physcultopathy, or naturopathy: *Provided, further*, That the practitioners of these systems prescribe in accordance with the art, science, and philosophy of the curriculum of their respective systems.

BRIEF OF CLARENCE E. ELDRIDGE, VICE PRESIDENT, YOUNG & RUBICAM, INC

At the time of the public hearings, before the Senate subcommittee, on Senate bill 1944, Senator Copeland invited interested parties to submit their views and suggestions in written briefs for incorporation in the record of the hearings.

This brief is being submitted pursuant to that invitation.

Young & Rubicam, Inc., is an advertising agency, located in New York City. It places advertising in magazines, newspapers, on billboards, and on the radio to the extent of several million dollars annually. Prominent among its clients are several of the largest and best-known food manufacturers in the United States. However, the suggestions and views presented in this brief are our own and are not presented on behalf of, nor as representing, necessarily, the views of any of our clients.

Let us say at the outset that we are opposed to the abuses that have existed, and that now exist, in advertising; that we subscribe whole-heartedly to any intelligent attempt to promote "truth in advertising."

As has been pointed out by the sponsors of the pending bill—and as has been pointed out many times by people whose business is advertising—the falsity of some advertising tends to lessen the belief in, and, therefore, the effectiveness of all advertising. From a purely selfish standpoint, therefore—from the standpoint of self-preservation and of the perpetuation of our business—we are opposed to false and misleading advertising.

But that is not the only reason for our opposition. We believe the public is entitled to protection against the fraudulent and misleading representation of goods offered for sale, not only advertised but unadvertised products, and not only foods, drugs, and cosmetics, but all products offered to the general public.

No one, we believe, can advance any valid argument as to why the public should not be protected against the "misbranding" of foods, drugs, or cosmetics. And, again, we subscribe without reservation to the contention that false advertising of those products—no less than false branding of them—should be prohibited.

The point at which we diverge from the philosophy of the proposed bill as presently drafted, and from the reasoning which its sponsors use in justifying its present provisions, is this:

We believe that such false advertising—both on the label and elsewhere—can be effectually prohibited without at the same time jeopardizing the business or the interests of any legitimate and honest manufacturer, publisher or advertiser.

That the proponents of the present bill do not agree with that belief is, we think, fairly obvious both from the language that they have used in drafting the "misbranding" and "false advertising" provisions, and from the arguments that they have used to support the language used. Their position is, quite evidently, that the public needs protection—that they are unable to devise language that will protect the public and at the same time protect the honest manufacturer—and that since the interests of the public are paramount, the public must be protected at all events, even although in protecting the public, the interests of honest and legitimate individuals and businesses must suffer. Additionally, of course, they minimize the seriousness of the threat to honest advertising—because they say that the law will not be enforced as written, but will be enforced only in part, so that its penalties will seldom fall on those who do not merit them.

To restate our position: We agree that the public is entitled to, and needs, protection from false advertising of foods, drugs, and cosmetics; we agree that the public interest is paramount; we agree, therefore, that if both the public interest and legitimate business cannot be protected at one and the same time, the interests of such business must give way to the protection of the public generally. But we by no means concede that the one cannot be protected and the other adequately safeguarded at the same time. And we contend that the protection of the honest advertiser should be contained in the language of the statute itself, and not depend on anything so illusory and untrustworthy as a promise that the law will not be strictly enforced.

In support of our belief that a provision that can be drawn that will protect both the public and the honest advertiser, we suggest the following definition of "false advertising" which we believe will prevent all the abuses which it is the avowed purpose of the so-called Tugwell bill to prevent; and which, at the same time, will make possible the honest exploitation of legitimate foods, drugs, and cosmetics.

"An advertisement of a food, drug, or cosmetic shall be deemed to be false if (1) it is in fact untrue as to the ingredients, the harmlessness, or the therapeutic, nutritional, dietetic, or health value of such food, drug, or cosmetic; or (2) if by inference fairly and reasonably drawn from the advertisement, it is misleading as to the ingredients, the harmlessness, or the therapeutic, nutritional, dietetic, or health value of such food, drug, or cosmetic; or (3) if either by its statements or its implications it materially misrepresents the product which is the subject of the advertisement.

"An advertisement of a food, drug, or cosmetic shall be deemed to be false if it unfairly or untruthfully disparages a competitor or the product of a competitor; and for the purposes of this section it is immaterial whether such disparagement be by direct statement or by inference reasonably drawn from the advertisement.

"Nothing in this section shall be construed or interpreted to mean that any advertisement of a food, drug, or cosmetic shall be deemed to be false or misleading merely because such advertisement contains claims of the kind recognized at common law and by the court as 'trade-puffing'."

With your permission we should like to discuss:

1. Wherein the present language of the Tugwell bill, in its zeal to do the one thing—namely, protect the public against false and misleading advertising—fails inexcusably to do the other important thing—namely, protect the honest manufacturer and advertiser.

2. The adequacy of the substitute language we have suggested to accomplish the purposes of the bill without punishing the innocent as well as the guilty.

I. THE OBJECTIONABLE FEATURES OF THE TUGWELL BILL IN ITS PRESENT FORM

It is not our purpose to discuss all of the respects in which we think substantial revision of the Tugwell bill is desirable. We prefer to confine our discussion, in the main, to those provisions which relate directly to advertising and branding.

In the first place, we think we can in this way help to conserve the time of the committee. Moreover, we are familiar with advertising, as we are not familiar with many of the other subjects covered by the bill. We can speak from experience, as specialists, on the effect of the proposed bill on advertising, whereas we could claim no such special knowledge with respect to the other subjects.

Nevertheless, before proceeding to amplify our position with respect to the definition of "misbranding" and of "false advertising", we wish merely to

enumerate a number of serious and fundamental faults which seem to run through the entire bill:

1. It seeks to confer upon the Secretary of Agriculture the power to make the law, to enforce the law, and then to judge the alleged violations of the law. It thus seeks to combine in a single administrative official, legislative, executive, and judicial powers.

2. In many respects the bill fails utterly to define an offense—merely conferring upon the Secretary of Agriculture (by virtue of his authority to make "regulations") the power to define the offenses which the bill presumably is intended to prohibit.

3. Thus not only administrative but law-making power is clearly sought to be delegated by Congress to an officer of the executive arm of the Government.

4. It seeks to substitute a hearing before the Secretary of Agriculture for the judicial process by which alleged violators of the law are entitled to be tried. As to many acts prohibited by the bill, not only are the findings of fact by the Secretary of Agriculture "conclusive if in accordance with law" (whatever that may mean) but, seemingly, the only case in which the courts would have any authority to reverse the Secretary would be those in which the judgment of the Secretary was so palpably wrong that it could be said to be capricious and an arbitrary and flagrant abuse of his discretionary powers. No trial de novo is provided for. The Secretary's findings may be contrary to the preponderance of the evidence—yet if there is any evidence to support his findings, we understand the bill to mean that the finding cannot be disturbed by the courts.

5. It deprives the accused of a trial by jury for an alleged criminal offense. It deprives him of "due process of law." It reverses the time-honored presumption that a man is innocent until he has been proved guilty. It reverses the equally time-honored tradition that where one is being tried for a criminal offense, the burden is on the Government to prove guilt; this bill seeks to shift to the defendant the burden of proving his innocence. This attempted shifting of the burden of proof is one of the more glaring iniquities of the entire bill.

6. The bill likewise seems designed to abolish another time-honored safeguard in our criminal jurisprudence: To wit, that it is better that 99 guilty persons go unpunished than that 1 innocent person should be punished.

Let us now return to the specific subject matter which this brief is intended to discuss, namely, the provisions with respect to "misbranding" and "false advertising."

There are two major respects as to which the definition of "false advertising" in the Tugwell bill is objectionable—when read in the light (1) of the abuses which the bill is designed to correct, and (2) of the avowed purpose of the spokesmen for the bill, in promoting it:

1. It makes no attempt to differentiate between misleading statements (or implications) as to things affecting the public health, on the one hand, and harmlessly misleading statements with respect to such things as color, appearance, convenience of preparation, flavor and the like. In other words, it seeks to outlaw not only harmful misstatements—misstatements that concern matters germane to a Pure Food and Drugs Act, but all other matters, however unrelated they may be to the protection of the public health, and however immaterial or harmless they may be.

(Let us make clear at this point that we are not defending the morality or the ethics of false statements in any advertising, on any subject matter. What we are saying is that the primary purpose of grouping foods, drugs, and cosmetics in a single bill is that they all affect the public health; that therefore the advertising claims (for a food product) that should be regulated in a pure food and drugs act are those that relate to health. This, as we understand it, is a bill to protect the public health—not a bill to regulate advertising. For obviously, if it were a bill designed primarily to regulate advertising, it should regulate all advertising, or at least the advertising of all of the necessities of life, such as clothing, fuel, transportation, electricity, building materials, real estate, and many other things. And since this is a bill primarily to protect the public health, each of its provisions, including the one pertaining to advertising, should be read with that purpose in mind; and each provision should be subjected to the two tests: Is this provision adequate to protect the public health, as to this particular matter; and, does it actually go further than the necessities of the case require, and prohibit acts which are not at all germane to the purpose of the law?)

2. It makes no attempt to differentiate between an inference justifiably drawn from the reading of an advertisement, and an inference that is utterly unreasonable.

In offering this criticism, we are assuming, of course, that the word "inference" is properly used in the bill and that it is not, as has been supposed by some of the commentators on the bill, inaccurately used as a synonym for "implication." Since "inference" is what the reader understands an advertisement to mean, and has no necessary relationship to what the advertisement says or implies, it is obvious that the advertiser has no control whatever over what inferences any given reader may draw from his advertisement. And quite as obviously, therefore, he ought not to be in a position where he can be put in jail, and his business ruined, because of some utterly unwarranted inference that may be drawn from a perfectly fair and truthful advertisement. The only thing that he should be held responsible for is inferences that are reasonably drawn from his advertising. And he should be held responsible for those kind of inferences.

The first of these two points seems to us to be of tremendous importance. If we are right in assuming that the purpose of the bill is to safeguard the public health and to protect the public against misrepresentation, then the bill should be so drafted that it does that, and nothing more. If, on the other hand, it is the unavowed but actual purpose of the sponsors of the bill to go further than that—if it is their purpose, under the guise of protecting the public health, to attempt to exercise broad regulatory powers over all the advertising of food, drugs, and cosmetics—then that fact should be frankly admitted and universally known.

When we seek to ascertain just what is the purpose of the bill—at least as it relates to branding and advertising—we find seemingly conflicting evidence. On the one hand, we find the language of the bill itself, which seems to contradict the avowals of Mr. Tugwell, Dr. Campbell, and the others. It seems to say that this is a bill not only to protect the public health, but to bring all advertising (of food, drugs, and cosmetics) under the absolute power of the Secretary of Agriculture. It seems to say, and does say, by the inclusiveness of its language, that "trade-puffing" is to be illegal and criminal; it says that any misstatement, however irrelevant, however innocent, however unimportant, however unrelated to the public health, shall be a criminal offense.

The sponsors of the bill disavow any such intention. Their position, as we understand it, is this:

1. Horsetail-weed has been sold as a cure for diabetes; horse liniment has been advertised in such a way as to imply to the less sophisticated reader that it is a cure for tuberculosis. The present law does not provide adequate protection against such misrepresentation. Therefore, additional legislation is needed.

2. It is not possible to anticipate all the cases that may arise. On this point Mr. Tugwell has said recently (Editor & Publisher, Sept. 6, 1933): "If the language of a statute is carefully restricted to just those cases of wrong-doing which its drafters can anticipate, the discovery of loopholes in the law is inevitable, and the difficulties of its enforcement will be multiplied manyfold."

3. Therefore, it is impossible to follow the well-recognized precedent of so drafting a criminal statute that it specifically and clearly and without ambiguity defines the offense to be prohibited. However, they say, this is unimportant. Even though the law itself is so worded as to condemn harmless and innocent, as well as wrongful, acts, and even though no manufacturer or advertiser can know in advance with any certainty what is permissible and what not—the honest advertiser will find his protection in the fairness with which the law will be enforced. The policy of the Department of Agriculture has always been fair and liberal in the past; there is no reason to suspect that it will be any different now. Therefore, there is no reason for alarm on the part of anyone except wrongdoers.

4. Mr. Tugwell and Dr. Campbell have both stated repeatedly that the bill if passed, will not prohibit "trade-puffing." The Department of Agriculture does not consider trade-puffing illegal; neither, they say, does the Supreme Court of the United States. And therefore, in spite of the fact that the bill as drawn does without a doubt make trade-puffing illegal, no concern need be felt on this point—because the Department of Agriculture will not enforce the law so as to punish or prohibit "the prideful boasting" that has always gone by the designation "trade-puffing."

5. And, finally, they contend that "the weight of a strict statute, intelligently enforced, will seldom fall on others than those who merit penalties." (Tugwell, Editor and Publisher, Sept. 13, 1933.)

If we accept at their face value all of these protestations, as of course we should, if we give to the authors of the bill credit for complete ingenuousness and sincerity,

their arguments in support of the present language still fail utterly to be convincing. In fact, some of their contentions are so opposed to the whole philosophy of our criminal procedure as to be utterly amazing.

Let us discuss their contentions seriatim:

1. We agree whole-heartedly that if horse-tail weed is being sold on the representation that it is a cure for diabetes—whereas in fact it is not—such misrepresentations should be prohibited and punished.

2. We agree that it is impossible to anticipate the specific cases that may arise; but it is not impossible to define the offense in general language that will give adequate notice to everyone as to what is and what is not illegal—and that will provide no loopholes for the wrongdoer. We grant that the enforcement of any law would always be easier if we were to confer blanket powers upon the enforcer to decide, first, what the law shall be, and second, what parts of the law he will and what parts he will not, enforce. But we think that mere ease of enforcement is not the ultimate desideratum in the framing of criminal statutes.

3. We can think of no doctrine more subversive of law observance than the one implied in this contention. It says in so many words that the law will not be enforced—but that only such parts of the law as happen to conform to the current views of the Secretary of Agriculture will be enforced. We have seen the extent to which the nonobservance and nonenforcement of certain laws have contributed to a serious disrespect for all law. Care should be taken to draft laws in such a way that they prohibit only those things that are intended to be prohibited —and in such a way that they can be observed and enforced as written. And the fact that the officers to be charged with their enforcement may be very paragons of intelligence, rectitude and impartiality does not alter this fundamental truth.

4. The argument that neither the Department of Agriculture nor the Supreme Court of the United States sees anything illegal or harmful in the "prideful boasting" that has gone under the name "trade-puffing"—and that therefore the proposed bill is not intended to affect "trade-puffing"—seems to us a little less than wholly sincere. It is very true that the Supreme Court has recognized "trade-puffing" and has found nothing in it that is illegal either under the common law or existing statutes. But since "trade-puffing" usually is not strictly and literally true "in every particular—since to that extent it is false and potentially misleading—it does come within the scope of the condemnation of the language of the Tugwell bill. And does Mr. Tugwell or Professor Campbell mean to imply that because the Supreme Court has held trade-puffing to be unobjectionable in the absence of any law making it illegal, that Court would hold similarly in construing a statute that does by its very inclusiveness make it illegal?

5. Here, it seems to us, is where the utterly untenable philosophy of the sponsors of the bill finds it most significant expression. Read this amazing argument: "the weight of a strict statute, intelligently enforced, will seldom fall on others than those who merit its penalties."

Waive the requirement of "intelligent enforcement." Assume, if you will, that its enforcement will be beyond reproach. They still admit, by clearest implication, that sometimes—if only "seldom"—its weight will fall on those who do not merit its penalties. Better that the innocent should sometimes suffer, than that a wrong-doer should ever escape. This, indeed, is a new concept in American criminal jurisprudence.

We do not believe the American people are ready for any such philosophy as the sponsors of the bill are contending for. And we do not believe that the adoption of any such philosophy is necessary in order to end the abuses that we all want to see eliminated.

The contention has been advanced, by the sponsors of the Tugwell bill, that honest advertisers have nothing to fear; and it has been implied, quite unmistakably, that any manufacturer or advertiser who opposes the bill—or any of its provisions—is thereby lining up with those who are willing to sacrifice the public health to private profits.

Let us see whether this contention will stand up under rigid scrutiny.

We have compiled an exhibit of food advertisements taken from the December issues of the leading women's service publications, the most reputable and ethical of all publications, to see what effect, in actual practice, a strict enforcement of the proposed terms of the Tugwell Bill would have. And we are of the opinion that there is scarcely a food advertisement in the December Good Housekeeping,

McCall's, Ladies' Home Journal, Woman's Home Companion, Pictorial Review or Delineator that could qualify under the language of the proposed statute.

Most of these advertisements, in our opinion, are completely unobjectionable. Few, if any, of them are untruthful, either directly or by implication, as to any material fact. Few, if any, of them are misleading in such a way that they are, or could be, harmful to the health of the public. Most of them are guilty, if that be guilt, of "trade-puffing." And probably not one of them could have been published, if the Tugwell bill had been law, without the advertiser's having run a risk of prosecution for "false advertising."

Let us cite a few examples of advertisements that are in fact "untrue in any particular", but of which it cannot reasonably be said that they should be made unlawful under a pure food and drugs law.

Pillsbury's Pancake Flour (McCall's, December): "Most of the grief in marriage starts at the breakfast table. Breakfast is the big sharp rock in the matrimonial seas. The best protection you can carry aboard your ship of romance is a large package of Pillsbury's Pancake Flour. * * * For there's nothing any man or woman likes better than pancakes—and no pancakes have quite the flavor you'll get with Pillsbury's Pancake Flour". "Pillsbury's Pancake Flour—the secret of happy homes."

Calumet Baking Powder (McCall's, December): "Cut a lice of that Calumet cake. Feel a bit between your finger and thumb. Soft as velvet! Then touch the cut surface. See how it springs back, tenderly moist and elastic. Now taste it. Velvet fine, velvet smooth! * * * creating cake as marvelously light and delicate as a cloud!" "* * * How to make flaky biscuits, muffins without 'tunnels', perfect pie crust, never-fail frostings, and meringues."

Pet Milk (McCall's, December): "Experts unanimously agree that Pet Milk candies are the easiest to make, the finest textured and the least expensive. Follow the Pet Milk candy recipes, and you can't fail to make delicious candy. * * * as good and delicious as anybody ever made. * * * fudge that melts in your mouth."

Royal Baking Powder (McCall's, December): "In homes of good taste—you will almost invariably find Royal Baking Powder."

Quick Quaker Oats (McCall's, December): "Here's richer flavor." "So delicious that it is preferred above all others." "Just the finest, plumpest grains." "A supremely delicious flavor." "* * * distinguishes them from all other oatmeals." "There's no other oatmeal like Quaker." "None have succeeded in copying the rich savory flavor." "Then watch the whole family smile at breakfast."

Eatmor Cranberries (McCall's, December): "The clever woman will always serve fresh cranberry sauce." "* * * and increases the palate appeal of every food it accompanies."

Smithfield Ham (McCall's, December): "Once you taste Amber Brand Deviled Smithfield Ham you'll go 'um-m', it's so good." "This famous delicacy gets a tremendous hand wherever it's served." "* * * sublime—* * * enchantment."

Gold Medal Flour (McCall's, December): "* * * the simplest, easiest and surest way to baking success." "Gold Medal 'Kitchen-Tested' Flour banishes the cause of most baking disappointments" "For, it is tested in an oven just like yours, for uniformity of results, before it goes to you." "Thus, every sack acts the same way. Results are perfect every time!"

"Never in the history of America did women respond so enthusiastically as to the first contest to find a name for a new Betty Crocker cake to be featured in a national advertising campaign."

Gold Medal Flour (Good Housekeeping, December): "Costing $25,000 to collect and publish * * *" "* * * to put at the command of every woman all the wizardry, the sorcery, all the subtle art of cookery that genius employs to enchant men."

"What your husband has to say about this Angel Food Waldorf will bring the roses to your cheeks."

Red and White Stores (Good Housekeeping, December): "Your Christmas Dinner—an assured success when you buy at a Red & White Store."

Lea & Perrins (Good Housekeeping, December): "Sometimes a lamb chop is timid."

Log Cabin Syrup (Good Housekeeping, December): "It brings the North Woods to your breakfast table."

Clabber Girl Baking Powder (Good Housekeeping, December): "I save you money and give perfect baking results."

Pillsbury's Best (Ladies' Home Journal, December): "Nowadays many a girl knows more about fox-trots than oven temperatures. What of it? Inside every bag of Pillsbury's Best you'll find a baking combination that works perfectly for amateur or expert, for 'old hand' or newly wed."

Campbell's Tomato Soup (Ladies' Home Journal, December): "Its flavor has never been equaled."

Sun-Maid Raisins (Ladies' Home Journal, December): "No other raisins can equal Sun-Maid quality." "The fresh, rich flavor of Sun-Maid Raisins cannot be equalled. Their cleanliness and convenience of use cannot be duplicated."

Not one of the foregoing advertisements is in the slightest degree a menace to the public health. Not one of them can be said to be guilty of misrepresentation. Not one of them could reasonably be objected to. And yet every one of them violates the definition of "false advertising" in the Tugwell bill.

Of no consequence, in our opinion, is the assertion on the part of Mr. Tugwell and Dr. Campbell that it is not this kind of "trade-puffing" that the Tugwell bill is designed to prevent. The fact is that the Tugwell bill does declare statements of the sort just quoted, to be false and therefore unlawful. Of no consequence is the promise that the bill will not be so interpreted in its actual enforcement by the Department of Agriculture. No official can bind the Department irrevocably as to its enforcement policy or any other policy. The bill must be judged by what it says, and not by the assertion by some protagonists that some violations will not be punished—that the law will be enforced only in part.

We think the public is entitled to a definition of false advertising that will prohibit and will punish false statements that jeopardize the public health, or that by misrepresentation deceive the public as to any material fact about the product; and we think the manufacturer and advertiser is entitled to a definition that lets him know in advance exactly what is illegal and what is not—a definition that means what it says—and a definition that is intended to be enforced as written.

Such a definition, we think, is the one that we have suggested on page 4. It outlaws any misrepresentation—direct or implied—as to ingredients; it makes unlawful any representation that a product is harmless if in fact it is not; and it definitely proscribes any claims—directly or by implication—that the advertised product is "good for" anything which it is not in fact "good for." Under this definition, a false statement or implication that a food has nutritional value that it does not have, can be punished and prevented; or that it helps to overcome constipation, or lack of energy, or nervousness, or sleeplessness, or any other physical ailment. These, if we correctly understand the purposes of extending the "false labelling" provisions to other forms of advertising, are the objectives of the advertising provisions.

Such a definition as we have suggested will give ample protection to the public—and at the same time it will not, in our opinion, work any hardship on honest business. It is definite and unambiguous—and it does not include within its prohibitions such exaggerations as are harmless, immaterial and utterly unrelated to the purposes of the bill.

II. THE DECLARED PURPOSE OF A PURE FOOD AND DRUGS ACT IS TO PROTECT THE PUBLIC HEALTH. YET THERE IS SUBSTANTIAL EVIDENCE THAT THE SPONSORS OF THE TUGWELL BILL HOPE, BY MEANS OF THIS BILL, TO ACCOMPLISH ANOTHER AND RADICALLY DIFFERENT OBJECTIVE—NAMELY, THE CONTROL OF PRICES BY REDUCING EXPENDITURES FOR ADVERTISING. THEY ARE FRANKLY OPPOSED TO ADVERTISING AS BEING "SOCIALLY WASTEFUL." IT IS IMPERATIVE, THEREFORE, THAT THE LANGUAGE OF THE BILL BE SUCH THAT IT WILL ACCOMPLISH ITS OSTENSIBLE AND OPENLY-AVOWED PURPOSE, AND THAT IT WILL NOT BE CAPABLE OF MISUSE IN A DIRECTION WHICH NEITHER THE CONGRESS NOR THE PUBLIC EVER INTENDED

Our argument, up to this point, has been predicated on the assumption (1) that the purpose of the bill is exactly what its sponsors avow, namely, to safeguard the public health and to protect the public against misrepresentation of material facts—and nothing more; and (2) that the sponsors are sincere in their contention that if the bill is passed in its present form—with its broad and unprecedented grant of powers of law-making, of regulation, of enforcement and of judging violations—it will be interpreted and enforced liberally and sympathetically, and in such a way as to cause no disturbance to honest business and honest advertisers.

And we have shown that even granting the correctness of those assumptions, the language of the bill is objectionable and should be revised.

Now, however, it is pertinent to consider an entirely different question: "What is the real purpose of the Tugwell bill?"

There has been an almost universal disclaimer on the part of manufacturers, publishers, advertisers and other opponents of the bill, as presently drawn, of any opposition to the "purposes of the bill." They all admit the paramount importance of the public health—and they agree as to the necessity for strengthening the pure food and drug laws so that the public health may be protected. The opposition has centered around method, not principle or purpose.

All of which makes the extent of the divergence of opinion between the sponsors of the bill, on the one hand, and its opponents on the other, quite incomprehensible. How can it be that two groups of people—agreeing as to the object to be accomplished—can disagree so widely, and sometimes so acrimoniously, as to the means to be employed?

This suggests an inquiry as to whether there is complete agreement as to purpose. What is the purpose of the bill? Is it merely to protect the public against deception and harmful misrepresentation, or is there some additional purpose, not declared, which its sponsors have in mind, and which furnishes the true explanation of language otherwise seemingly inexplicable?

In all frankness, we think there is at least some substantial evidence to justify the belief that the bill has a purpose, not declared and not in any way related to the protection of the public against false claims. We think there is evidence that an attempt is being made to utilize the Tugwell bill—ostensibly a pure foods and drugs bill—to effect social and economic changes which (by the sponsors' own admission) could not be accomplished in the broad light of day.

The sponsors of the bill admit that its language is broader than its enforcement will be. However, they say, honest advertisers need not fear—for the policy of the Department of Agriculture in the past has been fair, and it will continue to be so in the future. Therefore, they say, you can safely entrust the enforcement of the law to us—and we will enforce only those parts of the law that are needed in the protection of the public interest.

Since they are asking for so broad discretionary powers, it is important to know more about their attitude toward business—honest business—and toward advertising. It is important to know whether they have any "ax to grind" that is being kept under cover. For the acceptability of Mr. Tugwell as a dictator of what the manufacturer can and cannot say in his advertising depends to a much greater extent on what Mr. Tugwell's views are, generally, than on what Mr. Tugwell says in pleading for the delegation of broad powers.

And a careful reading of Mr. Tugwell's The Industrial Discipline justifies the feeling, we believe, that we should not want to entrust him with autocratic power over advertising. Such a reading seems to us to justify the following conclusions with respect to Mr. Tugwell's social theories and the extent to which he seeks to use the Tugwell bill for the advancement of those theories:

1. Mr. Tugwell thinks that three things are necessary to sound economy: Higher prices to producers of raw materials, higher wages to labor, and lower prices to consumers. He thinks that only in this way can consumption be stimulated and markets expanded.

2. These things, taken together, seem somewhat paradoxical—for they imply a narrowing of the spread between the price received by the producer and the price paid by the consumer. But Mr. Tugwell favors accomplishing this seeming paradox by (a) reducing the profits of the processor, the manufacturer and of other middlemen, and (b) reducing the cost of advertising and other sales and distribution effort.

3. His advocacy of the reduction in advertising and selling expense is perfectly consistent, of course, with his opinion of the place of advertising in the economic scheme. Honest market expansion, he thinks, can come only through decreased prices; and advertising is all "more or less, an attempt to escape the necessity of honest market expansion through decreased prices." And again: "It is doubtful whether nine tenths of our sales effort and expense serves any good social purpose."

4. He believes, therefore, that low prices are economically necessary; and that one way to bring down prices is to eliminate a substantial part of the advertising and selling expense. He believes, furthermore, that in the "plan for a national economy" control of prices will be an important plank.

5. He recognizes, however, that because of the Constitution there is no way in which the Federal Government can now legally control prices; he admits frankly

that it would be impossible to get the necessary public support for an amendment to the Constitution permitting such control; and he therefore admits the necessity for "exploring" to see whether there are available some "half-recognized and feebly-used means" by which his purpose can be effectuated.

6. And because of the constitutional limitations, and because of the "spasmodic and unpersistent" social will—"if", indeed, "there is a social will in the matter"—he admits frankly his willingness to resort to "subterfuges", to "devious approaches", to "stretching" available instrumentalities beyond their recognized uses.

7. The Federal police power may be such an instrumentality, he thinks. The Federal Pure Food and Drugs Act, he says, is a monument to what can be done with "the extension of this idea"—that is, of a Federal police power. Theoretically, of course, the Federal Government has no police power—but actually, under the guise of regulating interstate commerce, it has acquired—in the Federal Food and Drugs Act—actual police power. Under this act, he says, the public is protected against adulterated goods—which is one important bit of needed protection; but not yet has the Federal Government done anything to protect the public against exorbitant prices. And this injury to the consumer's pocketbook, he thinks, is just as serious an injury as the threat to its health.

Now the pattern of his thinking becomes complete and clearly comprehensible. He wants lower prices. Competition, which theoretically keeps prices down, actually does not. Therefore, prices must be controlled. The Federal Government has no constitutional power to control prices. Amending the Constitution, to grant the necessary power, "seems far off indeed"—first of all because it is always difficult to amend the Constitution, and second because there is no "social will" for such price control. Nevertheless, although there is no power to control prices, and no recognition by the public of the need or desire for controlled prices, he still thinks that such control must be effected if possible. If the power to regulate interstate commerce can be stretched to include power to protect the public health, why cannot it also be stretched to include the power to protect what is just as important—the consumer's pocketbook? It can—and in the same act. Not directly, to be sure. Not openly—but covertly, insidiously, resorting to subterfuge to obtain acceptance of what would not be accepted under its true colors—resorting to "devious approaches to what seems a simple problem."

In this philosophy, we think, may be found the explanation of some of the extraordinary language of the proposed Tugwell bill. It explains, as no other explanation has yet done, the tenacity with which the sponsors of the bill hold out for language far more drastic than seems to be necessary to accomplish the admitted purposes of the bill. The right to control the kind of advertising, Mr. Tugwell presumably thinks, will quickly become the right to control the amount of advertising. And we believe that here, at least, he is right. We believe that a strict and literal enforcement of the language of the Tugwell bill as to false advertising would surely result in a drastic curtailment in the amount of advertising. We do not believe—as Mr. Tugwell does—that such a reduction would be in the public interest. We do not mean to argue, at this time, the social and economic value of advertising—we wish only to say that advertising can and does reduce prices (by making possible mass production, with all its known advantages).

We have no quarrel with Mr. Tugwell's desire for high wages, high prices to farmers, and low prices to consumers. We share his desire. But if we correctly interpret the extent to which he is trying to "use" the Tugwell bill for the accomplishment of that purpose, we do there differ with him most sharply.

If the only way in which his three major objectives can be obtained is by conferring upon the Government the power to control prices; and if, in the exercise of that price-control, advertising must be controlled—curtailed—eliminated: then let him state the issue squarely and frankly and let the people decide. We are still a democracy. The people ought to be premitted to say, in the last analysis, what powers they wish the Government to have. We very much fear that the medicine which Mr. Tugwell seeks to administer by means of the Tugwell bill comes dangerously near to being "misbranded." We do not believe the public needs a guardian—yet; nor that it needs its medicine sugar-coated, or otherwise disguised.

Furthermore, we think Mr. Tugwell is wrong in seeking to control prices by so indirect and roundabout a method as by controlling the advertising of foods, drugs, and cosmetics. Why, if prices are to be controlled, should food, drugs, and cosmetics be selected—and other necessaries of life (real necessaries, such as many foods, many drugs, and most cosmetics are not!) be ignored? To protect the

consumers' pocket-book by controlling—or eliminating—the advertising of food, drugs, and cosmetics, would (even if Mr. Tugwell's low opinion of the usefulness of advertising were entirely justified) be a mere drop in the bucket.

Other means are at hand for accomplishing the desired objectives—means that are suited to the end to be attained—means that are honest and aboveboard: The National Recovery Administration, for example, is proceeding intelligently and effectively in the direction of higher wages—more money for consumers; the Agricultural Adjustment Administration is moving simultaneously in the direction of higher prices to farmers for their products—more money for this large group of consumers; the monetary program is designed to make more equitable the burden on debtors—another big segment of the consumer-group. But all of these forces are proceeding openly and honestly in the direction that they are supposed to go.

To the extent that social or economic changes are desirable, by all means let us have them. But let us get them honestly. Let us know what we are doing—and let us vote intelligently and with our eyes open on the extent to which the existing order is to be modified.

Let us not "back into" a new social order—let us not adopt it without knowing that we are doing so.

It may be of interest to examine the "record" to see whether our reading into the language of the Tugwell bill, Mr. Tugwell's philosphy of social planning, is justified. Accordingly, we are presenting, in an appendix to this brief, relevant quotations from this "The Industrial Discipline."

III. Conclusion

1. The definition of "false advertising" and similarly of "misbranding" should be so worded that they will effectually stop the abuses and the dangers that they are designed to stop; but that they will not go beyond the avowed purpose of the bill in an attempt to promote by indirection a new social theory which if appearing in its own clothing would be acceptable neither to Congress nor to the public.

Appendix

In this appendix we have attempted to paraphrase the pertinent facts of Mr. Tugwell's philosophy (as revealed in "The Industrial Discipline"), and in each case have quoted directly from the book in supporting the paraphrase.

I. Competition can no longer be relied upon to keep prices at the necessary low levels; therefore, the control of prices is "the protection of consumers in their most vulnerable interest."

Thus (p. 178 et seq):

"We still hear echoes in many places of the old belief that fair or just prices can only be established by the processes of a free competition * * * But there is a new attitude growing up concerning markets and prices which has a different end in view. It stresses the results desired rather than the mechanism by which they are attained; it has to do with the consequences of the pricing process. Since all goods and services are priced, incomes and standards of living are determined in the process. We are not so certain any more that so vital a concern for society ought to be left to the vagaries of the market. There seems to be no chance that even "justice", which might be done if competition were free, will—as things are—result from this process. The market is controlled, but the control is exercised by interested parties in a haphazard way. The idea grows that the national income and its apportionment is a matter which ought not to be left without some social supervision."

II. Moreover, it is necessary to limit profits.

For (p. 183):

"A nation of well-paid workers, consuming most of the goods it produces, will be as near Utopia as we humans are ever likely to get. It is necessary to this result that too much income shall not go to profits; for, if it does, this will either be spent for wasteful luxuries * * * or will * * * be distributed by bankers to enterprises who will over-expand their productive facilities."

III. Since low prices are good policy, and since there seems no way of assuring low prices without Governmental control, Government control will be a part of the program of social planning.

(See pp. 185 et seq.:)

"A number of problems concerning social policy are raised by these considerations * * * There are conflicts which enter into price relationships and

which, when left to the compromise of opposed forces, may or may not be settled satisfactorily * * * The only genuine alternative to conflict is, in this field, control, a policy, to be sure, which displeases most Americans, who are so jealous of the individual rights that they prefer society to suffer rather than invade any person's traditional prerogatives. If these prerogatives, however, tend in the direction of undermining social institutions we may, in time, be forced to make many concessions.

"One thing seems fairly clear; low prices are good policy, not only for consumers, but for industry as well. Here, of course, we run again on to the distinction between business and industry, or, if it is preferred, between good individual and good social policy. * * * It is apparent that what may be good business may also be bad economics. Public policy will ultimately be founded on good economics, and business will have to conform. The sooner this happens, the better for all involved. When it does happen, it might perhaps be safe to guess that the social direction of capital allocation and price control will be two features of the program."

IV. But, granting the importance and desirability of controlling prices, there are many practical difficulties in the way: The Constitution, the fixedness of relationships between the Government and business, and the difficulty of making any changes whatever in the direction of greater social control.

(See pp. 192):

"Our form of government is fixed in a series of formal relationships so difficult to change that alteration almost never occurs. Matters of deep emotional stress, such as prohibition was, can override all difficulties. And so we get an occasional, though infrequent, amendment. But the workaday world is a prosaic affair. The price of bread or the profits of a shoe manufacturer are not charged with emotional content. And so there is no amendment which relates to industry. If there is a social will in the matter, it is spasmodic, unpersistent, and results in few new institutions. The whole field of industrial regulation is left to the definition of the courts—and they are, to speak very mildly indeed, conservative."

V. Nevertheless, a national plan is necessary—one that will substitute control for the "utter failure of laissez faire" and the "miserable chaos of economic affairs." But because of the difficulty of amending the Constitution to make such a plan legal, it may be easier to examine the extent to which existing weapons can be "stretched" for the purpose of accomplishing the same purpose. We must use the instruments that are at hand, even though they may be antiquated and not entirely suited to the purpose. We shall have sometimes to use what seem like rather devious approaches. Some subterfuge may need to be employed.

"(These considerations) cause many social theorists to feel that it is a legitimate function of the Federal Government to make and execute such a national plan. * * * It is undoubtedly within the Federal power to prepare such a plan; the difficulties would arise when it came to be put into effect.

"If industries were to be controlled, incorporation of business enterprises would need, in effect, to be transferred from the States to the Nation, though some subterfuge might need to be employed; * * * prices would have to be controlled; and some vital interests, now partly or wholly neglected, would need to be protected. These last would include the weaker businesses, consumers, workers, farmers, and technicians. * * *

"Those who denounce in certain terms the utter failure of laissez faire and the miserable chaos of affairs—especially economic ones—which, they say, has followed insidiously upon its decline, are willing to work for such a change in opinion as will lead the public to accept the logic of its own attitudes, to substitute the specific and the practical for the general and the futile.

"That victory is still to be won; but there seems sufficient probability of final acceptance, at least, to warrant further exploration of possibilities. There are those who will say that what the public actively desires, it will find ways to achieve; but it is worth noting that such achievements are easier if some scouting is carried on ahead of the event, if possibilities are explored and experimented with in the imagination. One possibility is constitutional amendment. But that seems far off indeed.

"Are there ways in which existing institutions can be used to attain the same results? On the whole, it is better to make use, so far as that can be done, of familiar instruments; it is easier to persuade people to acceptance if what is to be done can be shown to involve, not something new and untried, but merely the extension of present half recognized and feebly used means" (pp. 201–302).

"The instrument with which we have to work is * * * poorly suited to its purpose. * * * The State cannot control; the Nation is not permitted to do so. Such a situation is ideally suited to the defensive purposes of those who want nothing done. And the problem is made doubly difficult for those who do. For not only does the desirability of doing it have to be demonstrated, but also the ways in which it can be done, without Constitutional limitations. Our reformers are faced with the necessity of using an antiquated instrument to accomplish their ends. This is the reason why for what sometimes seems rather devious approaches to simple problems" (pp. 217–218).

VI. One of these "subterfuges"—one of the "devious approaches" to which it is necessary to resort—is the extension of the idea of "the Federal police power."

We cannot constitutionally control, directly, the prices of food products—nor the profits of food manufacturers. Yet, in the interest of our basic philosophy, such control (according to Mr. Tugwell) is highly desirable. Advertising is wasteful—and adds to the price paid by the consumer—and detracts from the price received by the farmer. "Branding, elaborate packaging, inflated claims to special quality, with exaggerated ballyhoo, are all, more or less, attempts to escape the necessity of honest market expansion through decreased prices. It is doubtful whether nine tenths of our sales effort and expense serves any good social purpose." Therefore, in the interest of price control, advertising should be controlled, probably sharply curtailed, perhaps abolished. And this can be done deviously, by subterfuge, without letting the public know that something new and untried is being experimented with, under the guise of "protecting the health of the public."

Thus:

"As to the making of shoddy, misrepresented, or adulterated goods, it has been easier to enlist Federal interference. The Pure Food and Drugs Act stands as a monument. It shows, moreover, what can be done with an extension of the idea of a Federal police power. Why this cannot be stretched [sic] to include the protection of other vital interests, admitted to be injured, must be left for explanation to the more subtle minds among constitutional lawyers. Perhaps it is a greater or a different injury when one is forced to buy misrepresented bread or shoddy clothes than it is when one is forced to pay an exorbitant price for them; but to the lay mind, the difference is too narrow to fathom. Ideally, competition is supposed to prevent both; actually, it prevents neither. But one injury we outlaw, and the other we do not" (p. 195).

STATEMENT BY MRS. HARVEY W. WILEY, PRESIDENT DISTRICT OF COLUMBIA FEDERATION OF WOMEN'S CLUBS

At a regular meeting of the District of Columbia Federation of Women's Clubs, the following motion was passed:

The District of Columbia Federation of Women's Clubs endorse the principles of bill S. 1944 and recommend its passage without substantial modification.

The District of Columbia Federation of Women's Clubs consists of 29 clubs composed of about 5,000 members, here in the Nation's Capital. The members of my federation have given careful study to the provisions of the bill amending the present food and drugs law. The great majority of them believe that bill S. 1944 embodies all the provisions and spirit of the old law but that it stops the gaps and eliminates the compromises which Dr. Wiley was obliged to accept in 1906, in order to get any law at all. This bill leaves open the way for control of new foods, drugs, and cosmetics which may be invented or compounded in the future. Some of the most important of the new provisions I know were recommended by Dr. Wiley himself. Among these were the authority to establish legal food standards, the control of cosmetics, and the requirement for more informative labeling. Everyone seems to be unanimous in the demand for an amendment of the old law to meet the changed conditions of the last 27 years. We feel that no other bill can be as

disinterested as this bill, drawn as it has been by the officials of the Food and Drugs Administration, after 27 years of enforcement experience. Believing that its various provisions have been drawn to protect the consumer we hope that it may be passed without substantial modification.

I submit for the record a copy of a speech delivered by me on this bill before the District of Columbia Federation of Women's Clubs.

(The speech follows:)

During the 3 weeks since our last meeting so much has been said and written about the proposed bill amending the present food law that it now seems the wise and courageous thing for clubwomen to do is to sift the wheat from the chaff and to support the administration bill, S. 1944, framed in the United States Department of Agriculture by responsible and experienced food officials. To make any progress we must stand by a definite measure. Someone has got to draft a specific bill to embody the principles which everybody is clammoring for. Who is better fitted to do this than the enforcing officials, who from actual experience know the loopholes of the present law? Mrs. Ellis Logan's motion wisely says to endorse the principles of bill S. 1944 and recommends its passage without substantial modification. This motion admits of changing words here and there but preserves the actual motivating principles of the bill.

The new bill embodies all the provisions and spirit of the old law, but it stops the gaps and eliminates the compromises which Dr. Wiley was obliged to accept, in order to get any law at all in 1906. This bill also leaves open the way for control of new foods, drugs, and cosmetics which may be invented or compounded in the future. To amend the old law by grafting on the new provisions would have been to create a hodge-podge. Some of the most important of the new provisions were in fact recommended by Dr. Wiley. Among these were the authority to establish legal food standards, the control of cosmetics and the requirement for more informative labeling.

I want to answer some of the objections made to the bill recently at the New York State Federation meeting on November 15. The New York State Federation did not endorse the Tugwell bill but went on record as favoring the objectives of the bill and appointed a special committee to make a further study of the measure. This action was brought about by the statement of a Mr. C. Houston Goudiss. At the top of the paper on which Mr. Goudiss' speech is typed are the words: "Information Committee, The Proprietary Association, 80 Varick Street, New York City." The Proprietary Association is an association of patent medicine manufacturers.

Mr. Goudiss said: "Early in my career I came under the benign influence of the late Dr. Harvey W. Wiley. I was privileged to support him in his work; to fight with him against unscrupulous opposition. * * * Were Dr. Wiley alive today, I am sure that he would be standing here, instead of me. And if I presume to wear his mantle, it is because I feel that the great urgency of the situation calls upon me to do so."

I have never heard Dr. Wiley mention Mr. C. Houston Goudiss, and inquiry at the Department of Agriculture discloses the fact that no correspondence between Dr. Wiley and Mr. Goudiss between 1905 and 1911, when Dr. Wiley resigned, is on file.

Mr. Goudiss opposes bill S. 1944.

(1) He begins by opposing the term "general agreement of medical opinion" in regard to the misbranding of drugs (sec. 8 (a) (2)). At the hearings it was conceded by the authorities that they were willing to insert the word "contemporary" before "medical opinion."

Enforcing officials point out that the only reasonable source of information about the effectiveness of a medicine is in the medical profession. They cannot secure such information from lawyers, clergymen, or engineers. They further point out that the terms of this bill require first that they establish that there is an agreement of medical opinion and second that the medicine under consideration makes curative claims contrary to this agreement. If there is no agreement of medical opinion regarding the efficacy of a medicine the Government will have no case against it.

(2) Mr. Goudiss says this bill puts too much power in the hands of the Secretary of Agriculture. Every law has to indicate some enforcing official. The enforcing official, no matter who he is, has to delegate the job to some person in his bureau to do the work. In the past Secretary James Wilson abated 6,202 of the 9,866 cases reported by the Bureau of Chemistry between 1907 and 1911 as alleged violations of the law. At that time the Bureau of Chemistry initiated the proceedings in regard to adulterations and misbrandings but Secretary James Wilson prevented the prosecution of two thirds of all cases recommended for trial. (See the speech of Hon. Ralph W. Moss in the House of Representatives, Feb. 27, 1912. Government Printing Office 31771–10629, 1912, p. 11.) So an appointive official can circumvent the law for the protection of the public if he wants to, no matter how the law reads, but I believe that the great majority of our public officials are fine men. To those who claim that to make standards, place factories under a permit system, to enter factories for purposes of inspection, to enjoin a manufacturer from further violations of the law places too much power in the hands of the Secretary, it is well to remember that it is a rule of the Supreme Court that any regulation or standard made as a result of congressional authority to do so, must not be unreasonable, capricious, or arbitrary, and besides, all conferred authority is subject to review of the courts.

(3) Mr. Goudiss says that the bill will prevent self-medication. There is no basis for this statement. Self-medication, on the contrary, is to be made safe by this bill. Nine people out of ten will not take time to read this bill for themselves. They will hear a statement like this and then go and telegraph their Congressmen against the bill. And if enough such telegrams are sent they will kill the bill.

One lady told me yesterday that it would be impossible to buy a bottle of listerine without a doctor's prescription, under this bill. This will not happen. Listerine has gained its recent vogue on a campaign of fear. It does not cure halitosis. It merely changes a chemical odor for another odor. Under this bill druggists will be able to make a quicker turn-over on their shelves. They will not have to carry such a great number of seldom-used proprietary medicines. This bill will prevent advertisement or labeling of medicines for cancer, tuberculosis, diabetes, arthritis, and other diseases, which are incurable. It requires medicines which are not cures to be labeled to show that they are not cures but palliatives.

(4) Mr. Goudiss says that formulae disclosures will result in "confiscation of highly valuable trade assets." Today many proprietary medicines have their ingredients stated. All medical preparations exported into South America are compelled to have their ingredients stated. Anyway, any good chemist can find out by chemical analysis what is in a secret preparation. Some people are sensitive to aspirin, or acetanilide. They should know what they are taking. The bill requires informative labeling which information a customer has a right to know. It prohibits fraud and prohibits the sale of poisonous cosmetics and drugs.

(5) Mr. Goudiss told of a man who spent $20,000 perfecting a spaghetti sauce. This man it is suggested might be ruined by label disclosures. The bill merely asks that the principal ingredients be stated, flour, dried milk, eggs, fats, flavoring, etc. The trick of making the sauce is not disclosed. Any housewife wants to know the character of the food she is buying. Women are becoming more and more persistent for information on labels. Diabetic persons must avoid sugar. Others have an idiosyncracy for eggs. They want to know what is in the preparations they are buying.

(6) Mr. Goudiss predicts that the Tugwell bill if enacted would jeopardize the jobs of 2,000,000 workers. I cannot believe that that many people are engaged in occupations calculated to deceive the public; but if they are, then they should be stopped. I believe the great majority of our business men are high-minded, conscientious, and striving to serve the public interest.

I have been told that this bill would put an end to the chewing-gum business, where it is stated that a food is an adulteration "if it is confectionery and contains nonnutritive substances" (sec. 3 (c)). The Food and Drug Administration is willing to add to the list of exceptions to this article, "except coloring and flavoring and masticatory substances used in chewing gum."

Mr. Robert M. Allen, former food official of the State of Kentucky, in a public letter to Mr. Goudiss printed in Insurance, November 14, 1933, page 155, says in reply: "I refer to your claim to have inherited Dr. Wiley's mantle. Your address, as reported, would make any and all connected with Dr. Wiley during his fight feel that you are even as far away from the hem of his mantle as the North Pole is from the South Pole. I have read the bill with care and when it is summed up it can be stated that its provisions include nothing more than the truth and the whole truth about what people take into their stomachs, or what is relied upon in the matter of disease, together with appropriate, fair, and practical machinery for putting this into effect."

There is much that could be said about the provisions of the bill with regard to advertising. Here, as with foods and drugs, the honest high minded advertiser need not fear this bill. Advertising can be truthful and efficient at the same time. It was carefully censored advertising, under Dr. Wiley's pruning knife, which made Goodhousekeeping Magazine so successful. He discarded millions of dollars' worth of advertising during his 18 years of censorship but that very high standard brought other millions to the pages of the magazine. How we all long for truth in advertising!

From every standpoint this bill is the desirable bill to stand back of. It is written from a disinterested standpoint. Its proponents have nothing to gain from its enforcement except a desire to protect the public. It has the administration behind it. What an extraordinary fact that is! Never before in my lifetime has any administration been actively back of a reform of the food law. From my intimate knowledge of Dr. Wiley's life and writings I am sure he would endorse the bill.

Mr. Goudiss presumed to wear Dr. Wiley's mantle when he made his speech before the New York State Federation of Women's Clubs and he said he felt sure Dr. Wiley would be where he was, namely against the Tugwell bill. Now I do not presume to wear his mantle. He was a doctor of medicine and began his study in a day when the whole countryside was his laboratory. He read medicine with old Dr. Hampton of Madison, Ind., and drove from house to house with Dr. Hampton in an old-fashioned buggy, later taking his M.D. from Indiana Medical College. He was a chemist of great ability. He took his degree of Bachelor of Science at Harvard in that subject and taught the science for many years at Indiana Medical College, Butler University and Purdue University. But most of all he was a man of courage. It was not his knowledge of medicine or of chemistry which made him the "father of the pure food law." It was because he had the courage to stand against the pressure of his time and insist upon the principles for which he fought. I do not presume to wear his mantle but I do bear his name and in the close association of 19 years of sharing his home I know that he would stand for this bill. His book "The History of a Crime Against the Food Law" was written in 1929 because he thought the officials of the Food and Drug Administration were too lenient. He believed that the measure was a punitive measure and not an educational one. He did not believe in a "tap on the wrist" and an admonition "to be good" when a manufacturer or any other person broke the law. He had many enemies because of the stand he took. But his friends and adherents loved him for the enemies he had made.

Many of us here today are Daughters of the American Revolution. I am one. We are proud of our ancestry and blood. But did those whose names we honor back in 1776 know the outcome of the stand they took? Was every issue clear cut and finished in all its details? I think not. They took their stand and pledged their lives and their sacred honor in behalf of a great general principle, that the people in this country should have the right to govern themselves. Only one third of the people then were patriots and two thirds were so-called "Tories," good enough people, who believed in the English Crown and did not want to lose their property. But if we are good members of the Daughters of the American Revolution we must be worthy of the courage of our ancestors and also stand for a great moral principle, the principle of truth in advertising, in the preparation of food, of drugs, and of cosmetics. Who fears the truth?

I don't say it is going to be easy to stand for bill S. 1944. But the time comes to each of us at some time to take a stand on some great question, whether it is popular or not. Do you remember what Saint John the Divine wrote under the influence of the Holy Spirit to the Angel of the Church of the Laodiceans, in the third chapter of The Revelation? "I know thy works, that thou art neither cold nor hot; I would thou wert cold or hot. So then because thou art lukewarm and neither cold nor hot, I will spue thee out of my mouth." Not pleasant words. I quote them to show that the time has come, in my opinion, to take a stand definitely for this bill, not just to join the general clamor for a good bill to amend the present abuses. If we wait until Congress meets there will be a whole flock of bills introduced by people interested in this or that. Can any other bill be as good as this one, as disinterested I mean? And if we wait until Congress meets we shall have lost our opportunity to raise our voice at the board meeting of the General Federation in January in favor of this measure born of 27 years of experience. Dr. Wiley's law was born of 23 years of experience in the Bureau of Chemistry. The proposed bill has 4 years more of enforcement experience in the Food and Drug Administration behind it than his.

I fortunately have no strings tied to me. I have no one near or dear to me in either patent medicines, advertising, or cosmetics and so I can speak quite impartially and say that I hope with all my heart and soul that the women of this Federation, the Federation of Women's Clubs of the Nation's Capital, will lead the way in the support of this bill, a bill to protect them and those near and dear to them from poisoning and fraud.

The First Lady of the Land has written a book entitled "It's Up to the Women". That idea certainly applies here. Who manufactures poisonous cosmetics which maim and kill? Who manufactures patent medicines with false and misleading claims, which bring on death because they prevent their users from getting correct advice? Who uses false and misleading advertisements to break down our buying resistance and make us the victims of fraud? Isn't it generally speaking men? The great body of women are homemakers and consumers. So it's up to the women, to us, to start house cleaning with the Tugwell bill.

STATEMENT OF J. W. HEBERT, OF YAKIMA, WASH., ON BEHALF OF THE PACIFIC NORTHWEST FRUIT AND VEGETABLE INDUSTRY

In offering these observations on the proposed new Federal Food and Drugs Act, the fruit industry of the Pacific Northwest desires to state emphatically that it unqualifiedly endorses the principle of the act; namely, securing to the American public wholesomeness and purity in foods, drugs, and cosmetics. In presenting these suggestions the industry is not seeking to avoid in the slightest degree its responsibility which it recognizes and acknowledges to the consuming public. It has thoroughly demonstrated over a period of years its desire and purpose to so conduct its own operations and processes as to meet the most exacting demands of the consuming public in the wholesomeness of its products. It fully appreciates the motives of the supporters of the proposed bill and is in entire accord with their aim and purpose. The succeeding criticisms are meant to be constructive and are directed to the methods by which the act as written proposes to achieve the laudable objectives of its supporters, and are in no sense to be construed as obstructing the aims and purposes of the act.

In this presentation we are primarily concerned with those sections of the act which apply to food. This new bill as we understand it is largely inspired by the need for stricter regulation of drugs and cosmetics. Without presuming to pass on the need for such legislation, we earnestly submit that foods are inherently different and could readily be classified as such under a separate act, or left under the present act. Convenience of administration under the same act is not sufficient reason for classifying foods with drugs and cosmetics and there is ample precedent in such acts as the Tea Import Act and the United States Grain Standards Act for such separate legislative action.

We submit that the present Food and Drugs Act can be readily amended to adequately protect the consuming public in food standards. Based upon it thousands of cases have been successfully prosecuted and precedents established which would in large measure become ineffective if the proposed law is substituted.

In our well-considered judgment no such drastic measure is needed to further regulate the food industry. Manufacturers and processors of foods are compelled, not alone by the Food and Drugs Act,

but primarily by the compelling force of competition, the demand of the public for a sanitary and healthful food supply, to adjust their processes to meet such exacting demands. Under the present law the highest food standards of any country in the world have been established and made a part of the public consciousness—especially that of the American housewife who demands the utmost in cleanliness and safety in the food supply she purchases for her household. It surely should not be necessary to penalize the great majority of honest, conscientious food manufacturers, processors and fresh fruit and vegetable growers by imposing on them the burden of supporting an expensive bureaucracy in order to apprehend and punish a small minority of offenders. We submit that if the present law is not adequate or is weak in some particular, which faults or insufficiencies are well-known to the regulatory officials who have had charge of the administration of the law for a long period of years, that it should be amended or revised in such particulars only and retained as the Pure Food Act, rather than set up an entirely new, untried and cumbersome system.

We submit that the proposed act is contrary to American principles of Government in that it sets up what is substantially a dictatorship that will affect every man, woman and child in the United States, and even goes beyond the confines of this country in its attempt to control exports. It is inconceivable that Congress would enact a permanent peace-time statute containing provisions which are contrary to American principles of Government and which in fact, would be a surrender of the legislative power itself and a limitation of the judiciary to the imposing of penalties without authority to develop and pass on the facts. The great broad principles of Government upon which this country was founded and under which it has grown and prospered are at stake in this act as written. Dramatic appeals to the emotions by ardent supporters of the bill should not be permitted to becloud this fundamental issue.

Addressing ourselves to the act itself as written, all references are to S. 1944 introduced in the Senate of the United States, June 6, 1933, by Senator Copeland. Assuming that food is not withdrawn from the proposed bill and a separate bill drawn, nor that the present bill will be amended as the Pure Food Act as suggested heretofore, we advocate that the following changes he made in the bill as written:

First. Section 2, paragraph (e), shall be amended to read: "The term 'interstate commerce' means (1) commerce between any State or Territory, or between points within the same State or Territory", etc., dropping out the words "and any place outside thereof."

The reason for this change is that it is unreasonable to require American manufacturers and processors of food products to meet standards and tolerances which are not requirements of the countries to which the food is exported. In the field of international competition, the American exporter would be greatly handicapped by this unreasonable restriction. The present act amply covers this point by the provision that such commerce shall not be in violation of the laws of foreign countries of destination. The fruit industry is seeking no evasion here as it is now under the Export Apple and Pear Act approved June 10, 1933, Public, No. 39, Seventy-third Congress, which authorizes the Secretary of Agriculture to regulate and enforce

compliance with the tolerances for spray residues established under the Food and Drugs Act of June 30, 1906.

Section 3: Change line 22, page 3, to read: "A food may be deemed to be adulterated."

The work "shall" is mandatory and leaves no opportunity for appeal and is unreasonable and unnecessarily restrictive.

Section (3) (a) (1): Change line 23, page 3, to read: "If it is or may be dangerous to public health."

The same addition should be made throughout the act wherever the word "health" is not preceded by the word "public." Congress should only concern itself with protection of the health of the public. Many common and generally healthful foods are known to be dangerous to the health of individuals who have an idiosyncrasy for such foods. To make it a law that food shall be deemed to be adulterated which may be dangerous to the health of such individuals would if administered strictly completely destroy some entire food industries. For instance, some sea foods cannot be eaten by many individuals without making them seriously ill. Similarly, many cases of asthma are known to be caused by eating such common foods and condiments as wheat flour, fish, eggs, mustard, etc.

Section (3) (a): Strike "may have" in line 6, page 4, and substitute "has."

It is manifestly unreasonable to declare a food adulterated merely because it "may have" become contaminated by its surroundings. It is a question of fact readily ascertainable whether it actually is contaminated, and should be subject to proof.

Section 6 (a): Strike out "or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetic." Thus section 6, paragraph (a), would read:

> A food, drug, or cosmetic shall be deemed to be misbranded (a) if its labeling is in any particular false.

In this laudable attempt to curb or prohibit misbranding the bill as written goes far beyond the question of fact and enters upon the field of psychological reactions. What is ambiguous and therefore misleading to one person may be perfectly lucid to another; and what may be inferred by one individual's mental impression may be entirely different from another's. All minds are not cast in the same mold, and there are all stages of mental acumen and discrimination. It is preposterous to make into law a statement that is the heighth of ambiguity itself. An example of what might happen under this section as drawn is exemplified in our fruit brands which have been in use for many years and are recognized and accepted the world over. The first grade is branded "Extra Fancy" and the second "Fancy." These designations are official; that is, a matter of State regulation as well as trade custom. It is entirely conceivable that under the act as written this might be held to be a case which by ambiguity or inference creates a misleading impression, and therefore the use of these long-established designations of grade abandoned with resultant losses of many hundreds of thousands of dollars invested in these brands.

Section 6 (b): Practically all our fruits are "in package form" and are now subject to laws, both National and State, requiring certain marks as to quantity of the contents in terms of weight,

measure, or numerical count. If the Secretary of Agriculture is now to be empowered to dictate these for fruits and vegetables, which are perishables and subject to shrinkage and unavoidable change in storage or transit, provision should be made for reasonable variations as a matter of law and not as a matter of regulation. We therefore suggest that fruits and vegetables shall be either exempted from this paragraph, as being fully covered in other laws and grade rules applying exclusively and in detail to our business, or that "reasonable variations" be made mandatory as applied to fruits and vegetables.

Section 7: Fruits and vegetables should be entirely excluded from this entire section by adding the words "other than fresh fruits and vegetables", to section 7, line 2, page 8. The section would then read:

SEC. 7. A food other than fruits and vegetables shall be deemed to be misbranded.

And so forth.

The reason for this is that our standards have been fixed by law and are a matter of long-standing practice to which the trade and consuming public have become accustomed. Moreover, in the handling, storage, and shipment of perishables, the industry must be allowed the use of protective materials such as paper wraps and liners, pads, cushions and caps and elevated lids to avoid mechanical injury by bruising and crushing with resultant spoilage. The public is fully protected by both State and National laws covering these matters.

Section 9 (a): Strike the clause "or by ambiguity or inference creates a misleading impression regarding such food, drug, or cosmetic", for the same reasons as advanced under section 6 covering "misbranding."

Section 10 (a): Insert the word "health" before "public", in line 24, page 14; also in line 7, page 15, for reasons advanced under section 3 covering "Adulteration of food."

There should be inserted in section 10 a clause granting the right of proper appeal from the rulings of the Secretary on outright prohibitions or the establishing of tolerances.

This grant of power is altogether too broad and is without precedent in American governmental institutions. There are many divergent opinions as to what is or may be injurious to public health, particularly in foods; what is accepted today by the highest authorities is discarded tomorrow. The decision on such a vitally important matter should not be left to one individual or his appointees no matter how conscientious or well intentioned they might be. Frequent changes in personnel of administrative officers under our elective system of government would be a constant threat to industries coming within the scope of this act. No food industry, which was subject to tolerances of one kind or another as many of them are, which tolerances might be changed or abolished by fiat could prosper. It would not dare to expand and its securities would depreciate. It is not enough that notice and hearing should be promulgated. Such hearings are too frequently perfunctory, a compliance with the letter of the law. The right of appeal from the rulings of an administrative official should be preserved to the American public. This observation; namely, the right of appeal does not only apply to this particular section but to all sections

giving the Secretary unlimited and unrestricted powers. The situation, as grave as it may be in particular instances, certainly does not warrant this broad, sweeping grant of authority which is tantamount to a surrender of the legislative power. This provision together with section 23 (c) which states "the findings of fact by the Secretary shall be conclusive", empowers the Secretary or his appointees to make the law and decide the facts which shall be conclusive, leaving the court only the power to enforce the penalty. As applied to a willful or vicious offender such a peremptory method of procedure might be excusable, but such offenders constitute a small minority in the food industry and to subject the great body of honest, conscientious food manufacturers, processors and fruit and vegetable growers to such a drastic procedure without right of appeal is contrary to the principle of law that one charged with a crime is presumed to be innocent until proved guilty. Surely this right is not to be extended to the vicious criminal element in the body politic and denied to those who inadvertently violate some highly technical or unproved theory made a matter of law under the act as drawn. The right of appeal from decisions of the Secretary as to matters of tolerance and findings of fact should be written into the act in the proper place.

Section 11 (Definitions and standards for food): Page 15, line 14, insert the words "other than fresh fruits and vegetables" after the word "food."

The fruit and vegetable industry already has its established mandatory grade standards under the Bureau of Agricultural Economics and State grade laws, and therefore have no place under the authority of food and drugs regulatory officials.

Section 12 (Permit factories): Fresh fruits and vegetables should be exempt from this entire section. The industry is already licensed as individual firms or individuals by the Department of Agriculture under the Perishable Agricultural Commodities Act of 1930 for which each shipper must pay a fee of $10 per year. The act in this section provides for another permit or license which the Secretary may impose on the industry under food and drugs regulations. The section further provides that the Secretary may make such regulations governing the packing as he deems necessary. We submit that this is an unwarranted extension of power. Under this broad extension of authority the food and drugs branch of the Department could dictate every operation regardless of the requirements of the trade and consuming public or the dictates of good business. It is sufficient that they be empowered to require a clean, wholesome, healthful food product, without being empowered to dictate how it shall be packed.

Section 15 (Investigations, etc.) (b): Strike the following beginning line 21:

or to whom any health, food, or drug officer of any State or Territory, or political subdivision thereof, presents evidence satisfactory to the United States attorney of any such violations.

All such actions in a Federal court should be instituted by officers and employees of the Department of Agriculture only, and not by local health, food, or drug officers. The reasons for this are too obvious to require argument.

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Section 16 (Seizure) (c): Line 22, page 21, strike "may" and substitute "shall."

It seems obvious that either party to a condemnation proceeding should have the right to obtain a representative sample of the article seized for purposes of prosecution or defense.

Section 17 (Penalties): There should be incorporated in this section a provision providing for remedial action by conference between parties in technical violation and the Secretary without penalties being imposed. Many cases of violation are involuntary and are excusable on the grounds of being only slightly in variance with some highly technical provisions which are subject to various chemical or bacteriological analytical tests. Such unintentional, and in fact, harmless violations of the law should be settled by conference and not subject the honest and conscientious shipper or manufacturer to court action and the harsh penalties of the law. These harsh penalties should be imposed on willful and unscrupulous violators which the law is primarily designed to apprehend.

Paragraph (2) of section 17 should be changed to read:

The receipt in interstate commerce of any food, drug, or cosmetic with knowledge or information that it is adulterated or misbranded.

And so forth.

It is manifestly unreasonable and would cripple industry and obstruct the normal flow of business to make a buyer of a food subject to severe penalties for merely receiving goods which were adulterated or misbranded without his prior knowledge or information.

Section 22 (Voluntary inspection service): The provisions of this section are highly objectionable on the grounds that it virtually compels every food manufacturer or processor or grower to install a Government inspector in his factory or packing house and then advertise to the world that his product bears the Government stamp of inspection. It saddles industry with a bureaucracy of inspectors, the cost of which must be borne by the individual manufacturer, processor, or grower, which in the aggregate is an added burden to the industry involved. If, however, such inspection of fruits and vegetables is made at point of origin and the commodity passed as meeting the regulations, then such certification at point of origin should be final. Growers and packers should not be subjected to loss of the product at destination after the heavy cost of transportation has been added, except, of course, in case of fraud.

Section 23 (c) (General administrative provisions): The findings of fact by the Secretary should not be conclusive as provided in the proposed act, page 31, lines 2, 3, and 4, for the reasons advanced under discussion of section 10. The charges of the Secretary in cases of seizure should be subject to proof in each case that the food so seized is or may be deleterious to health. Under section 10 the Secretary is authorized to fix official tolerances and under section 11 he is authorized "to fix, establish, and promulgate definitions of identity and standards of quality and fill of container" of any food. Section 23 (c) provides the findings of fact by the Secretary shall be final, thus the Secretary or his appointees become legislator, administrator, prosecutor, and judge. The findings of fact by the Secretary might be made prima facie evidence but should not be conclusive. The present law in case of seizure requires the Government to prove in each case that

food so seized is or may be deleterious to health, whereas under the proposed act all the Government would be required to do would be to prove the commodity seized exceeded the tolerance established by the Secretary who in turn determines the facts. We submit that the procedure under the present law is the correct one and is in keeping with American principles of Government. It is Government by law and not be edict.

Section 24 (Liability for personal injuries):

A right of action for damages shall accrue to any person for injury or death proximately caused by a violation of the act.

This is perhaps the most unwarranted and objectionable provision of the proposed act. The cases at law dealing with the subject of "proximate cause" are in the shadowland of legal precedent. To write into statutory law a recognition of "proximate cause" would be to throw open the doors of courts to a flood of fraudulent cases and encourage the racket of "ambulance chasing", a practice condemned by the American Bar Association and all reputable members of the legal profession. The party injured now has every reasonable protection under the law and a right of action for damages without deliberately prostituting the proper conduct of legal practice by such an unwise and unnecessary act. If the effect would be to bring only the willful, unconscientious, and vicious violator to the bar of justice it would be warranted, perhaps, but there would be no such discrimination practiced, and the honest and conscientious manufacturer and processor would be subjected to persecution virtually sanctioned by statutory law.

STATEMENT OF R. M. ALLEN, PRESIDENT OF THE ASSOCIATED COMPANIES VITAMIN FOOD CO., INC., AND VEGEX INCORPORATED, NEW YORK CITY

My companies and I can say all of the 4,000 stockholders support Senate bill 1944, the Tugwell bill under consideration. In addition to our support as good citizens and consumers of foods, drugs, and cosmetics, we earnestly wish the enactment of the bill to give confidence to advertising.

We sell vitamin products. Vitamins can neither be seen, felt, tasted, nor weighed on a scale. The selling must be on confidence. Advertising is the main sales method. Everything must be believed to get the consumer to purchase these new products.

The vitamins can, let us say, be compared to the spark plugs on the automobile. All must be present. It takes all to do the job.

Now, my company advertises that one of its products will furnish the vitamin B_1 and the vitamin B_2 (G) spark plugs. We place this advertising, let us say, in one of the leading women's journals. Now, in another column or on another page someone else with the vitamin A, vitamin D, vitamin E, or vitamin C spark plug advertises in a way to induce consumers to feel that their spark plug will supply all of the other spark plugs.

We advertise in the Journal of the American Medical Association. In order to do it we must not only confine ourselves to the truth and the whole truth in that advertising, but in all other advertising. So

that in doing this we want to see a Federal law which will confine everybody's advertising to the truth and the whole truth. Otherwise, fair competition and fair trade cannot be had.

Newspaper, magazine, and radio advertising are matters which the Federal Government should control. This whole activity extends throughout interstate commerce and the mails. A multiplicity of State laws on the subject, if differing in their provisions, will almost put a stop to all forms of food, drug, and cosmetic advertising.

Advertising which tells the truth is the cheapest selling for any product which has merit, but in order to be effective, confidence must attach to it. Purchasers must find that the advertised word is made good in the product.

My companies have spent a million and a half dollars in advertising. We were the pioneers in vitamin advertising. Out of this experience I am of the opinion that a Federal law which will attach confidence to advertising will, not substantially but enormously, increase particularly newspaper and magazine advertising and will in the same ratio increase the income of the advertising agencies.

It is impossible to appear without also appearing out of the experience which was had in 15 years of food and drug control work in Kentucky, a year as special assistant to the United States Attorney General, Mr. Bonaparte, and having served as secretary of the Association of State Food and Drug Control Departments from 1902 to 1910, which included the period when we worked with Dr. Wiley, with Senators McCumber and Hayburn and with Congressman Hepburn and Mann to secure the passage of the Federal Foods and Drugs Act June 30, 1906.

I feel sure that, if living, Dr. Wiley would be in strong support of this bill. He, like the rest of us, might suggest changes in this or that verbiage of the act. But, not only in general principle but in the way the provisions of the Tugwell bill are brought together, and brought together out of the experience of 30 years to accomplish the present-day job, this bill would have the support of those who worked with him for the enactment and enforcement of the present Federal law.

Among the objections to the bill is that it will confer undue power upon the Secretary of Agriculture.

As a matter of fact, the provisions of the act markedly restrict the powers which are already conferred under the act of June 30, 1906.

Under the existing act, the Bureau of Chemistry is given power to examine and determine what may be adulteration or misbranding. Under the proposed act the definitions of that which will be misbranding are extended. Then before the Secretary of Agriculture can charge that a new practice is adulteration or misbranding, regulations must be adopted, public hearings are had on these regulations, they do not go into effect for 90 days.

Before criminal prosecution is had under them the defendant must be given an administrative hearing, and every lawyer knows that when the regulation comes before the court it must be backed up by the facts or it will not stand.

Now, as it is today, the Bureau of Chemistry or the Food and Drug Administration may decide that this or that practice constitutes adulteration. They do not have to get out regulations about it.

They can bring criminal prosecution or seizure proceedings on the basis of their interpretations.

The power of the Secretary to adopt standards should be not only proposed but insisted upon by all engaged in the manufacture of foods, drugs, and cosmetics. There must be standard methods for analyses, otherwise we would be at the mercy of what the individual inspector or chemist thought to be adulteration or misbranding.

Further, there is no similar law of this character on either the Federal or State statutes which does not provide for administrative legislation. In fact the minimum railroad rate enacted by the State of Illinois was held unconstitutional because it did not provide machinery to find out what constitutes fair rates, thus placing the business of the railroads in the jeopardy of what the juries in this or that county might decide to be a fair rate.

The same applies to adulteration. Under this Tugwell bill we can all go down to Washington, discuss it with the chief of the Food and Drug Administration and his staff, discuss it, if we wish, with the Secretary of Agriculture, go back, file our briefs and, after the Secretary announces his regulation, we have 90 days in which to institute mandamus or other proceedings. Then if we are prosecuted with the regulation being the basis for the facts, we have a hearing and, finally, when at last we get to court, the regulation must, of course, be based on the facts or it will not stand.

For after all, conviction under a criminal law must be based upon the violation of some one of its provisions. The regulation must come within such provisions and must have to do with a set of facts which in the end must constitute a violation of the provision.

Giving some consideration to some of the sections of the bill in detail:

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It should be unnecessary to discuss sections 1 and 2. These give definitions of terms used in the bill.

Section 3 contains nothing with which any honest food manufacturer cannot comply and with all of which he should seek to comply in assuming the responsibility of preparing things for human consumption. Certainly no one would sell a food which is "dangerous to health" or "if it bears or contains any added poisonous or added deleterious substance prohibited, or in excess of the limits of tolerance prescribed by regulations."

The sanitary provisions in this section provide as follows:

> If it consists in whole or in part of any filthy, putrid, or decomposed substance; or if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.

A neighbor, president of a high-class firm engaged in the production and sale of salted and cured fish, and a graduate of one of the national universities, told me that he was very much concerned about the Tugwell bill because the sanitary provisions were impractical and could not be carried out even if the best care were taken in the handling of the fish from the catch boat to the final curing. I invited him into my office, read him this paragraph on sanitation, and we agreed together that it was not strict enough, except as regulations might and undoubtedly would make the paragraph protective.

The section is not as strict as the sanitary provisions written into the amendment of the Kentucky Food and Drugs Act of 1910. This provides that an article of food is adulterated—

> If it be produced, manufactured, or stored or exposed in a manner which may render the article contaminated, diseased, or unfit for food.

My friend then told me that those who were engaged in the fish business had received a letter from an association asking them to vigorously oppose the bill because it would make it very difficult for them to remain in business.

The rest of section 3 follows in the main the definitions of adulteration which are already included in not only the State laws but in most of the municipal ordinances throughout this country. These provisions have received interpretation by courts. Administrative regulations adopted under them have been perfected, sustained, and are in every-day observance. There is added the prohibition of such container as is deceptive in appearance as to weight and measure. Many of the States and cities already have such laws. There can be no honest objection to them. Administrative regulations adopted after opportunity for full hearing will give everybody a chance to know what may be expected under the law.

Section 4 introduces the new provision that the drug is adulterated—

> If it is or may be dangerous to health under the conditions of use prescribed in the labeling thereof.

This is a very important section. I would suggest introducing after the word "labeling" the words "or any other representations for the use."

Subsection B of section 4 continues the United States Pharmacopeia as the standard for drugs. This work is compiled and periodically revised by chosen leaders from the medical and chemical professions.

There is nothing else in section 4 but what both the pharmaceutical profession and the consumer need for their joint protections.

Section 5 introduces cosmetics. Let us read it. A cosmetic is adulterated—

> (a) If it is or may be injurious to the user under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.
>
> (b) If is bears or contains any poisonous or deleterious ingredient prohibited, or in excess of the limits of tolerance prescribed, by regulations as hereinafter provided.

Can there be one in that industry with any honest objection to the giving of this protection by the law to those who use cosmetics. In fact is there one among we men who would not be stirred to the depths and fight to the utmost if necessary to give this protection to the "school-girl complexion," facial beauty and charm of our mothers, wives, sisters, sweethearts?

There is nothing in this as has been pointed out by those in the cosmetic business who have led to oppose it which requires the disclosure of valuable formulas.

Section 6 under misbranding introduces in subsection A as a definition of misbranding—

> If its labeling is in any particular false or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetic.

It is said that the phrase "ambiguity or inference" will make it impossible for the copywriter of the advertising agency to know just what to write. In the first place, this does not apply to the copywriter of the advertisement but to the label. In either event when one writes a label or advertising copy out of imagination, instead of the well-established facts from products, one would get into trouble. Business itself has long fought against this colorable infringement of private trade marks; for example, those who seek to crawl up behind the henhouse on a dark night instead of walking through the front door in open daylight to steal a chicken. All forms of fraud are generally attempted under all possible means for concealment. This is the reason Sherlock Holmes has been so long exceedingly popular among readers of detective stories.

No one who seeks to tell the truth and the full truth about a product in getting up a label need have any fear of this section. Those who attempt otherwise will run their label into trouble.

A study of a long line of decisions of the courts relating to trade marks show how the protection afforded against infringement has not so much been against the open adoption of one man's trade mark by another but rather through trying to make a new trade mark look as much like an established trade mark as can be done without getting into trouble under the trade mark law.

Years ago Chief Justice Hargis, of the Kentucky Court of Appeals, in giving protection to the Avery Plow trade mark said (Browne on Trade Marks, second edition, p. 25):

> The trade-mark and the trade-reputation pirate always undertakes the difficult task of sailing between the Charybdis and Scylla of the law, but he should never be allowed a successful voyage. If on the one hand he escapes the rock by not infringing through the instrumentality of the trade mark itself, he will not, on the other, if courts of equity are true to the principles of their existence, be allowed a safe passage by the use of any means of deceit or false representation known to the inventive brain of man.

Is not the school-girl complexion, the growth of a mother's child, and the health of the mother and her husband entitled to the same protection in legislation which was given years ago to the manufacturer of plows?

Subsection B of section 6 is all right in fact, except that it introduces authority for the Secretary to follow such honest and trade practices in the canned-goods industry as now exist in the establishment of regulations under this section.

No one can object to subsection C which requires the labeling under the act to be plain and prominent.

Section 7 applies only to the misbranding of foods. This introduces the provision that a food for which a standard or definition has been adopted under the law and which in its labeling purports to be such a food, must comply with the standard of the food or tell where any different from the standard.

In cases where no standard for a food has been adopted, then the standard would be trade practice and consumers' understanding.

The last sentence in subsection E provides:

> The secretary is hereby authorized to prescribe by regulations requirements for such further information on the label thereof as he may deem necessary to protect the public from deception.

If there is any objection on the part of anyone to the Secretary doing this, and if it is not considered that such regulations would

come within the general provision of the act applying to regulations the words "in the manner provided for in section 11" can be added after the word "regulations."

Section 8 applies only to drugs. Cosmetics and food industries, except as they may sell their products for medicinal use, are not concerned.

Northwest Daily Press Association adopted resolutions against the bill, and have sent a copy to those who advertise, or have advertised, in these journals. There are 34 members of this association whose names appear on the circular. One "whereas" in this circular states:

> Whereas any movement that would prohibit and prevent normal self-medication, depriving persons of small means who cannot afford the high cost of medical care, any means of relief whatsoever, is contrary to public policy and is not for the general good.

No one who reads this bill can agree with the statement from the Northwest Daily Press Association. Instead of restricting the poor man in the purchase of medicines the bill seeks to protect the poor man in such purchases by having him told in the label and advertising the truth and the whole truth about the medicine, and further protecting him from the unknowing use of dangerous drugs and at all times from the unregulated use of narcotics.

In subsection 8 there appears,

> If its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.

Here again the question is whether we shall restrict the law to only such crimes against human health as are practiced in the open daylight and through the open door, or whether also the law shall seek to get at those who break a window, jimmy a door in the nighttime, or dig secret tunnels under and to the vault of the treasury of human health.

Those in the proprietary-medicine industry who have fought so hard to prevent infringement of existing trade marks, and who have relied on the rule of law laid down by Chief Justice Hargis, should not complain if consumers wish the same rule of law applied in relation to the descriptive terms and phrases used through which the consumer purchases medicine. In short if this rule of law already applies at the earnest insistence of able counsel who have protected trade marks of proprietary remedies from infringement, why should it not apply to the other words and phrases which describe what is in the trade-marked product and what it will do?

If there is any objection to the authority conferred upon the Secretary in subsection D of section 8, which provides,

> That the Secretary may by regulation exempt any drug from any requirement of this paragraph if he deems such requirement unnecessary for the protection of public health.

then insert after the word "regulation" the words "in the manner provided in section 11." This would give all concerned opportunity to be heard; in this particular case would give the consumers' organizations opportunity to be heard.

Subsection E of section 8 again provides:

> The Secretary is hereby authorized to prescribe by regulations requirements for such further information on the label of such drug as he may deem necessary to protect the public health.

Here, again, after the word "regulations", if there is any question in anyone's mind about conferring too much authority insert the words "in the manner provided in section 11."

Section 9 applies to advertising. In this section is the real reason for the opposition to the bill. The director of the advertising agency and the copy writer are afraid of the words "ambiguity and inference." But the fraud which the law seeks to break up is not open-front-door fraud else it could be quickly gotten, as far as newspapers and periodicals are concerned, under the fraud sections of the postal laws.

When in charge of the food and drug control work in Kentucky, I recommended, and the legislature of 1910 passed, a provision relating to the misbranding of medicinal preparations as follows:

> If it be labeled or branded, or in any manner represented as so, so as to deceive or mislead the purchaser or consumer with respect to the purity, quality, or medicinal value;

I drew up that section following a year and a half as a special assistant to the United States Attorney General in cases arising under the Federal Food and Drugs Act of June 30, 1906. I considered each and every word with care at the time. In drawing it up practically all of the decisions of the courts relating to adulteration and misbranding of foods and drugs were reviewed; trade marks and patent decisions were reviewed. Each word was chosen with the relationship to some decision previously handed down by the courts in such matters or related matters.

Whether the word "misleading" can bring behind it more of judicial interpretation than the words "ambiguity and inference" I have not looked into. But where the word "misleading" and the word "ambiguity" and the word "inference" or any other word is used there should be no doubt in the mind of any man or woman that the law plainly intends to provide against any form of deception in the labeling and advertising of foods, drugs, and cosmetics. And he or she who seeks to tell the whole truth and nothing but the truth will be surprised to find so much truth in connection with foods, drugs, and cosmetics, and so much need for this truth in the great selling field of human life that they will wonder why they ever turned to, or depended upon, in the past their imaginations, and their seeking to attach a colorable untruth to a product when, if there is any merit in the product, there is so much real truth to be told.

Subsection B of section 9, which provides:

> An advertisement of a drug shall also be deemed to be false if it includes (1) the name of any disease for which the drug is not a specific cure but is a palliative and fails to state with equal prominence and in immediate connection with such name that the drug is not a cure for such disease; or (2) any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion.

In recommending a drug as a palliative for disease, the consumer, let us say, a poor man, the unforgotten man, will be informed that it is not a cure, so that the poor man will be put on notice and not led to trust the all important machine to inadequate relief and mending and false security.

The list of diseases given in subsection C of section 9 are dangerous diseases. They represent that army of as yet uncontrolled diseases which are constantly warring against the health and life of children and grown-ups every day and everywhere. Earnest and able, well-trained men and women with utmost devotion in work and purpose in medical, biological, and bacteriological centers are constantly day and night working and working comparing, discussing, and confirming results, to lessen the volume of diseases and the toll in human lives which this army of diseases constantly takes. There can be no honest objection from anyone who understands this provision of the enactment into the law.

A tack in a biscuit is promptly followed with a demand for damages and a civil suit if damages are not paid. Foods, medicines, and cosmetics containing harmful ingredients which people cannot taste or see, or labeled and advertised with false claims, would run against the same drastic damage suits if the facts were as equally plain as the tack in a biscuit.

It is very easy in the technical and obtuse things connected with science and finance to fool enough people all of the time to make it very profitable.

State and Federal inspection laws are the only protection consumers have unless a professional firm made up of chemists, lawyers, and physicians should be organized to investigate and bring suits for damages where the medicine did not cure and could not cure, where the cosmetic harmed the complexion, or where the food did not have the growth-promoting properties for the child claimed in the label-advertisement, or over the radio.

Damage suits because of the more obscure harms contained in a food or drug, or which may be occasioned by following any untruth in its advertising, have not been had because of difficulty in getting and proving the facts.

More and more the people are having fact-finding facilities and the newspaper, magazine, radio, and advertising agency managements should already begin to give consideration to the matter of contributory negligence.

If I defended such a case I would be glad to have the guarantee provision which exempts liability on the part of such managements to plead collaterally in defense.

Some of the makers of proprietary medicines always cry out, when attempt is made to confine them to the truth, that physicians are trying to get the monopoly of the practice of medicine in their own hands and prevent poor people from getting cheap medicine. There is nothing in this bill which does this, but it would be a long step.

One of the most needed and effective things which could be done for the public health would be in the establishment of some organized system whereby each and every little and big human machine could be accurately examined to find out what is the matter with it before self-treatment or any other kind of treatment is attempted.

You take your watch to the jeweler, your automobile to the garage, not only for repair but to find out what is needed to be repaired. The missing link for those who label and advertise does not supply this accurate diagnosis. Among even everyday household remedies

aspirin temporarily relieves headache, a laxative temporarily relieves constipation.

The time has come when we ought to be getting in a proper way, and I cannot say without socialized medicines, at the prevailing causes of headache and constipation, and remedy these causes. The human machine is the most important and the most vital of all machines.

If those who are fighting continue to do the things to the human machine which they are doing should make the same fight to repair watches, automobiles, motors, railroad engines, and similar things, they would be laughed out of court.

While the physician is in no way given any advantage—as a matter of fact compelling the truth in all labeling and advertising may lead to the wider use of reliable remedies—he is entitled to fair trade just as I as a manufacturer am entitled to be protected from unfair competition. Had physicians not worked as earnestly and unselfishly as they have worked to find the cause of human diseases and end them, this country would need many times more physicians than we have and they would all be very busy. Working with the bacteriologist they have brought infectious and contagious diseases under control. Think of the typhoid cases doctors used to have and which they do not have now.

One of the old diseases which has been most recently attacked in an organized way is pellagra. My company is supplying a product used in the treatment of pellagra throughout the South. I am working not only with the health departments but with the doctors themselves. They are working hard and unselfishly to end pellagra, although pellagra has been year after year the source of a substantial part of their practice; a practice out of which some of them make but a bare living.

The physicians established certified milk for children. The very ones who had their large practice in the treatment of children worked the hardest to get certified and pasteurized clean milk, which put an end to what was formerly a very profitable practice.

Those who are loudest and most persistent in urging that a bill like this will turn medicine over to the doctor—as a matter of fact it really belongs to the physician and pharmacist and we would have far better health if such were the case—are also loudest in proclaiming that their remedy is used by thousands of physicians and in many hospitals.

In endowed medical centers and in private practice throughout this country and abroad, physicians are working with human clinics to find the cause and cure of such diseases as cancer. And when the cause and cure is found it will take away a large part of the practice which surgeons and others have in the application of the at present known means for relief. And while these medical centers are doing this and until they have found a cure for cancer, let the Government stop that fraud on human health which holds out this or that product for the relief or cure of cancer, and which has little or nothing which will do it.

PUBLIC INTEREST

During the fight for the passage and enforcement of the act of 1906 there was a senate of conference, so to speak, among the representa-

tives of the groups supporting the law. This was organized into the American Pure Food League. I was president of it. They asked me to continue, but I urged that someone who does not get, directly or indirectly, any income from the food industries, be selected.

But I was interested in the exhibit which the league made under the executive secretary, Miss Alice Lakey, at the Women's Exposition at the Hotel Astor, New York City, September 1933, of the misbranded drugs and cosmetics and misleading advertising, prepared by the Food and Drug Administration and the Department of Agriculture.

I checked into this exhibit on several evenings, watched it from the side lines. As secretary of the National Association of Officials and of the International Pure Food Congress, I organized the exhibit of adulterated foods and drugs which was made in the Hall of Agriculture at the St. Louis World's Fair. Mark Sullivan, in his second volume of Our Times, says that this exhibit was—

> The most effective bit of propaganda ever made for pure food or any other cause.

Benjamin R. Hart, a graduate of Kentucky State College, and one of our assistants in the pure-food work, and S. L. Darling, were selected to manage this St. Louis exhibit.

Hart stayed with us for part of the summer. Being at the exhibit got him a job as chemist for the city health department of St. Louis. Another assistant was taken by one of the large firms for their food exhibit in the department.

Sol Darling finished the summer with me. When the exhibit was packed up and we were looking at the bare walls and boxed exhibits throughout the rest of the Agricultural Building, Darling turned to me and said:

> We have kindled a fire of public interest in pure food which no power on earth will ever put out.

But the interest in that exhibit was small compared with the overwhelming, unanimous interest of the women who crowded in to Miss Lakey's booth at the Hotel Astor and all of whom were eager to register under a petition to Congress to pass this bill. And they were very representative women.

I made up my mind in connection with our exhibit at the Century of Progress to find out what the people are thinking about and what they want to know about foods.

Our staff talked personally to over 800,000, with a very large registration from those who wanted the feeding tests conducted at the exhibit and other facts about vitamins and nutrition, sent. I observed this crowd day after day while at the fair. I spent many evenings myself at the rail.

The demonstration shows that the people are hungry for the truth about foods and that they distrust all forms of advertising.

I spent many evenings myself at the rail talking to this and that group. The pure food laws and needed amendments, including this bill, were discussed with them. The committee can take it that the people are unanimous for the bill and that the only opposition comes from those who either do not understand it or who cannot remain in

business when the labels and advertising are compelled to state the complete truth.

Beginning in 1903 with the American Federation of Women's Clubs, American public sentiment was organized behind the McCumber-Hayburn-Hepburn-Mann bill in a way which enabled its leaders to carry it through the votes of the Senate and the House into the Federal statute.

A very much larger tidal wave of public sentiment can be put behind this bill. But is it necessary to do it? Should those who fought at much personal sacrifice, and practically out of funds from their own limited salaries as pure food officials, be again put up against having to go to the public about this bill? Should the big majority of honest food and drug manufacturers, who now put out honestly labeled and honestly advertised products, be subjected to that Nation-wide agitation which cannot but disturb public confidence in advertising?

In the June 26, 1931, issue of the journal, "Insurance" I stated:

> In Kentucky we watched milk during summer months. Inspectors, with helpful suggestions, stayed at the dairy until too late to see; bacteriologists left their laboratories only long enough to sleep. Charts, where vital statistics were available, were watched as closely as some watch the ticker tape during a market flurry. The death rate among babies had been lowered; first by a third, then one half and still lower. No compensation in honor or money can equal the satisfaction. Only two others know, the mother and doctor.

I also said in that article:

> The vitamin and other discoveries in nutrition have thrown more light and given sure direction to the work. In the facts reported by Osborne and Mendel, McCollum and Davis, Sherman and the several other hundred men and women in their field, out of the facts supplied from the dietitians and investigators in home economics, and in coming from medical centers, there is enough known to build the coming generation into a race of giants, to prevent a substantial part of every day common ills and to lengthen the youth and life span much farther than has been known.

Advertising which is filled with facts is the biggest, fullest, everyday way to carry this benefit into the everyday lives of men, women and children. But to do it, advertising must be the kind of advertising which tells the truth and the whole truth. And when the advertising agencies see this and do it, they will have opened up a new field which has far more copy space awaiting them than the field around which too many of them have constructed an imaginative halo, many of the acnodes of which never touch the everyday needs in human nutrition and human health.

STATEMENT OF W. PARKER JONES, WASHINGTON, D.C., GENERAL COUNSEL FOR NATIONAL CONFECTIONERS' ASSOCIATION

The National Confectioners' Association of the United States is in full sympathy with the objects sought to be accomplished by this proposed legislation, but suggests for your consideration that the bill as introduced may work undue hardship upon the confectionery industry and requires amendment.

By section 7 (f), confectionery becomes misbranded "If it purports to be or is represented as a food for which no definition of identity has been prescribed by regulations as hereinafter provided, and its label fails to bear (1) the common or usual name of the food, if any there be,

and (2) the common or usual name of each ingredient thereof in order of predominance by weight, except that spices, flavors, and artificial color may be designated as such without naming each spice, flavor, or artificial color.

Although definitions under the present act have been established by the Secretary of Agriculture for a variety of foods, no definitions have been fixed for confectionery. It may fairly be assumed that the reason for the omission is that there are more than a thousand different types of confectionery with a variety of ingredients in varying proportions. Any definition of confectionery as a class would necessarily be so broad as to be meaningless, and definitions of so great a number of different types appear to be impracticable.

The general provisions of the bill prohibiting false or deceptive labeling are believed to be adequate to preclude misrepresentation, and the provisions governing adulteration should be sufficient to prevent the use of any unwholesome ingredients, but the requirements of section 7 (f), that where no definitions have been established, the ingredients be named in the order of predominance by weight, would impose a great burden upon the confectionery industry without any benefit to consumers.

There are some few types of confectionery for which definitions are needed, such as chocolate-coated candies, marshallows, nougats, caramel, and jellies, but confectioners are continuously engaged in developing new pieces.

Consider a typical 5-cent bar composed of a fudge center, dipped in caramel, rolled in toasted peanuts and then chocolate coated. It can be covered by a definition for fudge, a definition for peanuts, a definition for caramels, and a definition for chocolate. But to what definition must this finished confection conform? Plenty of latitude must be had in the calculation of component parts in their order of magnitude.

The statement made for the complex composition of the novelty type confection will also apply to a nougat in which nuts, gum drops and, perhaps, a small quantity of fruit has been added. If this is dipped in chocolate and then rolled in toasted coconut, under what classification will it fall? The job of calculating raw materials in their order of magnitude in such a confection will not be an easy one and the purpose solved by such a calculation is not quite clear even though the results are included on the label.

Example after example can be cited where it will be almost impossible to state the quantity of materials in a confection in their order of magnitude. Slight variations will occur from day to day and even though the same quantity of materials are weighed into the cooking kettle, changes take place during the process which are not always comparable. To state further examples would only serve for emphasis.

In general, the definition of mixed confections is impossible. An assortment is rarely uniform, nor is it indicated that it should be, unless it is the intent of the proposed bill to prohibit the sale of new and novel mixtures.

Information required on the top of a package containing an assortment not covered by definitions will be so lengthy, so bunglesome, and so meaningless that any attempt to convey it will be absurd. This example has been referred to by many proponents of the bill as being an extreme case. In reality, it is an ordinary case, which can be proved by examining any of the mixtures, assortments, or selections to be purchased in the many retail shops. No doubt this contention will be answered with a promise that definitions and standards will be set. This, in itself, does not solve the dilemma. Let us suppose that all existing confections have been standardized. When a new, novel, and attractive product is manufactured, it will be necessary for the manufacturer to state materials used in their order of predominance by weight until a definition has been approved. This in turn will convey sufficient knowledge for a competitor to duplicate and offer a product in competition, which is admittedly unfair.

Confectionery should be exempted from the requirements of section 7 (f).

Under section 3 (a) (4), confectionery becomes adulterated "If any substance has been mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength or create a deceptive appearance." Much has been made of this statement, and in the "chamber of horrors" exhibited by the Food and Drug Administration, ice-cream dummies have been constructed showing relative sizes, along with figures which state the percentage of air contained. It seems that this is considered to be a gross act of adulteration. When a confectioner adds frappe to a fondant, he is doing the same thing. He is increasing its volume and making a finished weight appear to be larger than it would be if no frappe had been incorporated. When confectioners beat marshmallow, finishing with a weight of approximately 3½ to 4 pounds per gallon, they obtain results again comparable to those set forth as deceptive in the case of other products, but is it deceptive to produce and sell marshmallow? If this constitutes adulteration, the beaters now in use in every plant will have to be scrapped. In addition, it will become necessary to set a definite specific gravity at which all confections must be finished, in order that all volumes will be comparable in weight. This, of course, is absurd.

Under section 13, "Factory Inspection", it is provided that in order to regulate adequately interstate commerce in food and enforce provisions of the act, officers or employees, duly designated by the Secretary, after first obtaining permission of the owner, operator, or custodian, are authorized to enter any factory, warehouse, or establishment in which foods are manufactured, processed, packed, or held for shipment in interstate commerce or are held after such shipment or to enter any vehicle being used to transport such food in interstate commerce. If the owner, operator, or custodian has denied to officers or employees, duly designated by the Secretary, permission to enter and inspect the factory, warehouse, establishment, or vehicle and equipment, methods, processes, finished and unfinished materials, containers, and labels, there used or stored, the several district courts of the United States are vested with jurisdiction to restrain by injunction, temporary or permanent, the shipment in interstate commerce or delivery of products which have been manufactured. This may constitute a hardship to both manufacturer and duly designated employee of the Secretary alike.

If there was nothing to be lost by inspection, no possible objection could be raised to the presence of inspectors at any time in the plant of a specialty food manufacturer.

This, unfortunately, does not follow and in some cases such permission can be harmful. If the inspector or duly designated employee is certain to continue in such capacity for an indefinite period of time, then secret processes may be protected. On the other hand, if an inspector or duly designated employee elects to leave the service at an early future date, his memory may serve him in good stead. Processes with which he has become familiar by virtue of the discharge of his official duties can be utilized unfairly in competing with the very manufacturer whom he has inspected. It must be remembered that time and money are expended by progressive manufacturers in establishing plant practices, developing equipment, and producing goods which are individual in nature. These cannot be covered always by patent, even when desired, and it is submitted that a manufacturer has an equal right to protect information obtained as a result of research, whether it be by letters patent or secret process.

It is recited in section 14 that in order that the act may be enforced, carriers, subject to the Interstate Commerce Act, as amended (U.S.C., title 49), and other carriers engaged in interstate commerce and persons receiving food in interstate commerce shall, upon request of an officer or employee duly designated by the Secretary, permit an officer or employee to have access and to copy all records showing the movement in interstate commerce of any food and the nature, kind, quantity, shipper, and consignee thereof, and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any record so requested; provided that evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained. This provision is fair only if such records are kept in strict confidence. It can be turned into an invasion of the rights of private manufacturers and produce a leak which may be detrimental in so far as competition is concerned.

Section 21 of the proposed bill confers upon the Secretary of Agriculture the right to disseminate such information concerning any food as he may deem necessary in the interests of the public health and for the protection of the consumer against fraud. The power of the Secretary to disseminate information concerning any food should be limited to disseminating information concerning judgments of the courts.

Section 24, the provision conferring a right of action for damages upon any person for injury or death proximately caused by a violation of the proposed bill apparently creates no right which does not now exist. If construed to create a new right of action, the provision is out of place in this bill and should be omitted.

That part of section I of the present Food and Drugs Act which exempted exported wholesome foods from its labeling requirements, provided the foods contain no substance prohibited by the laws of the foreign country to which the foods are exported has no counterpart in Senate bill 1944. Exporters of confectionery should have the right to export confectionery which conforms to the laws of foreign countries free from restrictions imposed upon confectionery sold for domestic consumption, but not imposed by foreign countries upon confectionery manufactured or sold there for home consumption.

STATEMENT OF HORACE W. BIGELOW, GENERAL COUNSEL AND CHAIRMAN OF COMMITTEE ON LEGISLATION OF THE AMERICAN DRUG MANUFACTURERS ASSOCIATION

The members of this association (list of members attached) are representative of manufacturers of prescription products which are the medicines used by pharmacists in compounding physicians' prescriptions and by dispensing physicians who supply medicines direct to their patients.

By the very nature of their business, the members of this association have always been mindful of the necessity for the proper protection of the public health, the safeguarding of which is recognized by the members of this association as paramount to commercial or other considerations. Consequently, their attitude toward Senate bill 1944 has been governed by the necessity of the proper protection of the public health, as well as the safeguarding of the consumer.

We are in accord with the proposition that false advertising of medicinal products must be eliminated and that there is also a necessity for the control of the so-called cosmetic products. It has been our hope that these purposes could be accomplished by the amendment of the existing Federal Food and Drugs Act. This hope has been entertained because it is felt that a repeal of the existing law would result in the recall of many interpretative decisions of the courts, which have been handed down during upwards of the 25 years which have elapsed since the enactment of the present act.

Moreover, every member of this association has a Nation-wide distribution of its products, which brings them more or less under the jurisdiction of the food and drugs acts of the several States, which acts have been enacted over a period of years and to a greater or less degree in their form and substance follow the Federal act. It necessarily follows that if the present act is repealed, there will follow a period of years during which the several States will attempt by legislative enactment to bring their various laws into line with any Federal act which may be passed by the Congress of the United States. The turmoil and uncertainty resulting therefrom would, we believe, be detrimental to the manufacturers and producers of prescription medicinal products without serving the public interest. We have, therefore, been inclined to the view that if it were at all possible, the existing Federal Food and Drugs Act should be amended to accomplish the proper control of false advertising and the other matters which seem to require better supervision.

The proposed legislation which is now under consideration, does not amend the present act but completely repeals it, and is susceptible to the sound objection that by its terms it is an unwarranted and unjustified delegation of legislative power to administrative officers. Provision after provision and section after section contain powers of regulation with respect to specific problems, and finally in section 23 the Secretary of Agriculture is given additional broad powers of regulation which would enable him to write regulations at will having the full force and effect of law, thus submitting the drug industry to the whim and caprice of administrative officials.

In making this statement, we are not in any way reflecting on the present administrative officers, but are advocating the continuance of

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the sound principle that no Government administrative officer should have the power and authority to legislate by regulation. We do not deny the necessity of conferring upon administrative officers regulatory powers limited to the proper enforcement of the law under which such powers may be exercised.

It is believed that there has never before been a measure introduced in the Congress of the United States, granting such wide legislative powers to an administrative agency as Senate bill 1944. It hardly seems necessary to advance any further reasons for the necessity of the complete revision of this proposed measure than the sound objection which we have already enunciated. However, there are many specific objections to particular provisions of the proposed measure and we will attempt to enumerate some of the more important.

Section 4 (*a*) provides that a drug shall be deemed to be adulterated—(*a*) if it is or may be dangerous to health under the conditions of use "prescribed in the labeling thereof." Almost any drug may be dangerous to health. Even a normal dosage when administered to a patient with idiosyncrasies for certain drugs which appear to be free from possible danger, may be found overnight to be dangerous to certain individuals as in the case of Cincophen, and the careful use of antitoxins and serums which may be accompanied by unavoidable reactions. This form of definition might open the door to unjustifiable lawsuits against reputable manufacturers by designing individuals, even though there is no adulteration in fact within the commonly understood meaning of the term.

Also under this clause the physician may be deemed by the administrative officers to be liable under the prescriptions which he writes.

Section 4 (*b*) repeals the deviation clause as it is now found in the present Food and Drugs Act. The repeal or change of this clause has been consistently opposed by this association for years. At the third annual meeting of this association, held in 1914, Frank G. Ryan, then president of the association, made the following significant statement in his address:

> During the past year indications have appeared that an attempt will be made to amend the Pure Food and Drugs Law with a view of doing away with the so-called variation clause. To those who have not given careful study to this subject the suggestion may seem desirable; but when carefully exmained it will be found that its effect will be very far-reaching, and in fact will prohibit the sale of large classes of medicinal products, such as the mother tinctures of the homeopathic physician and specific tinctures of the eclectics, and any improved pharmaceutical or chemical product not conforming to the standards of the Pharmocopœia or National Formulary, thus stifling all progress in the manufacture of medicinal substances until such time as those in authority may see fit to recognize such improvements. With the few exceptions where the public are purchasers direct, pharmaceutical products are sold through the drug trade, or used by physicians who certainly should be able to read labels and decide for themselves what product is wanted, and a definite statement of the exact strength of a product distinctly on the label should be all that should be required. I recommend that this association go on record as opposed to any change in the Food and Drugs Act which will repeal the so-called "variation" clause.

Acting upon Mr. Ryan's recommendation, the association passed a resolution recording its opposition to any change in the act which would repeal the so-called "variation" or "deviation" clause.

Section 4 (*b*) also gives the power to the Secretary of Agriculture to change the tests laid down in the United States Pharmacopœia and the National Formulary. This question was very ably discussed by

Dr. James H. Beal in his address before the committee yesterday. We are convinced that the present system of revision of these official standards is sufficient to meet the requirements of enforcement officers, particularly in view of the expeditious manner in which the two revision committees may issue supplements changing, modifying, or adding to the official standards.

Attention is directed to section 6 (*a*) and the interpretation of what constitutes ambiguity or inference. This particular section was quite fully discussed and it is believed that the committee is thoroughly aware of the possibilities of drastic and dangerous interpretations under this paragraph.

The provisions of section 8 (*a*) have also been forcefully brought to the attention of the committee and we wish to emphasize the fact that there are exceedingly few medicines recognized by the medical profession as specifics in the treatment of any disease in the medical sense of the word, and it is entirely out of place in this paragraph. Certain drugs that are exceedingly useful cannot be classed as anything but palliatives. Just what would be considered a cure and what would be considered a palliative, is evidently left to the discretion of the Secretary of Agriculture.

Also, under this same section, it is provided that a drug shall be misbranded if its labeling bears any representation directly or by ambiguity or inference concerning the effect of such drug which is contrary to the general agreement of medical opinion. The chairman of the committee has evinced considerable interest in this particular provision and apparently has been asking some revision of the language of this section whereby a fair interpretation could be obtained.

Section 8 (*i*) attempts to cover the labeling of germicides, bactericides, disinfectants, and antiseptics. By his own statement Mr. Campbell made it perfectly clear that it would be impossible for the manufacturer of a germicide, bactericide, disinfectant, or antiseptic to comply with the provisions of this paragraph. It is obvious that it would be impossible for a manufacturer to market one of these products under the provisions of this paragraph, and we wish to emphasize the necessity of the elimination of this paragraph, not only from the proposed measure, but from any measure which Congress may enact. This type of product and the proper labeling thereof should fall under the general provisions of any act which the Congress of the United States may enact.

Sections 12 (*a*), (*b*), and (*c*) place in the hands of the Secretary of Agriculture unlimited, unjustified, and unwarranted power; but, if in the public interest and as a matter of sound public policy it is deemed necessary to include in the law provisions of this type and character, the power conferred upon the Secretary of Agriculture should be limited in its exercise to those cases in which after proper showing before a court of competent jurisdiction he has obtained an order from that court authorizing him to proceed to exercise such power. In other words, manufacturers should have their day in court.

As to section 13, providing for factory inspection, there may be need for such a power in the Secretary, but as in the case of section 12, we do not believe such a power should be exercised until and after the Secretary has been authorized by an order of a court of competent jurisdiction to proceed with such an inspection.

Section 16 enables an administrative officer to make seizures when he has probable cause to believe that a drug is so adulterated as to be imminently dangerous to health. The placing of such a power in the hands of an administrative officer would subject manufacturers to the constant danger of having their products seized without having an opportunity of protecting themselves from the prejudice, whim, or caprice of such an official. Moreover, this section protects an administrative officer who abuses his authority by providing that any judgment which may be obtained against him for illegal acts shall be paid by the Government.

Section 16 (c) leaves the matter of furnishing samples to the discretion of the court. It should be mandatory and the court should upon application of any party to any proceeding criminal or otherwise, as a matter of right obtain an order for the delivery of a sample to the applicant party.

Section 19 is objectionable because it would permit injunction proceedings against manufacturers involving products, the adulteration or misbranding of which had not been passed upon by a court of competent jurisdiction. Such proceedings should not be had until the question of adulteration or misbranding has been finally determined by the court.

Section 22 provides for a voluntary inspection service, and on the face of this section it might appear to be a very wise provision in the public interest; but upon careful analysis it will immediately be seen that every manufacturer would eventually be compelled to accept this voluntary inspection service in order to be placed upon a fair competitive basis with other manufacturers who accepted it and labeled their products in accordance with these provisions. This entire section should not be included in any measure which may be enacted by the Congress.

The foregoing are a few of the most objectionable features of S. 1944, but there are many more which we could bring to the attention of the committee. However, we believe that what we have said will suffice to convince the committee that the amendment of S. 1944 in order to make it a measure sound in principle, in law, and in public policy, is impossible. If this conclusion be correct, there remain open but two courses for the committee to pursue in meeting the legislative problem now before them. The two courses are:

(1) Amend the existing law in such a manner as to strengthen it to the extent that it will meet present requirements, or

(2) Strike out everything after the enacting clause in S. 1944 and rewrite it in such a manner as to make it sound in principle, in law, and in public policy.

With respect to the first course, there has been offered by the National Drug Trade Conference, of which this association is a constituent member, suggested amendments of the existing law. These amendments deal only with the drug provisions of the existing law and in no manner attempt amendment of the food sections. These proposed amendments, as we understand them, are merely suggestions subject to revision.

With respect to the second course, we have not had the time or opportunity to prepare and submit a complete revision of S. 1944, but we stand ready to render such assistance to the committee or to the Department of Agriculture as may be required to accomplish the proper amendment of existing law, if that be deemed to be the proper course, or to prepare a complete revision of S. 1944, if that be deemed the proper course.

Respectfully submitted.

MEMBERS OF THE AMERICAN DRUG MANUFACTURERS ASSOCIATION

Abbott Laboratories, North Chicago, Ill.
Armour & Co., Union Stock Yards, Chicago, Ill.
Bauer & Black, 2500 South Dearborn Street, Chicago, Ill.
W. J. Bush & Co., Inc., 370 Seventh Avenue, New York, N.Y.
G. W. Carnrick Co., 20 Mt. Pleasant Avenue, Newark, N.J.
Citro Chemical Co., Maywood, N.J.
Cole Chemical Co., Inc., 3727 Laclede Avenue, St. Louis, Mo.
The Cutter Laboratory, Berkeley, Calif.
Davies, Rose & Co., Ltd., 22 Thayer Street, Boston, Mass.
Digestive Ferments Co., 920 Henry Street, Detroit, Mich.
The Dow Chemical Co., Midland, Mich.
The Drug Products Co., Inc., 26–32 Skillman Avenue, Long Island City, N.Y.
Fairchild Bros. & Foster, 70–76 Laight Street, New York, N.Y.
Fritzsche Bros., Inc., 78–84 Beekman Street, New York, N.Y.
Heyden Chemical Corporation, 50 Union Square, New York, N.Y.
Hynson, Westcott & Dunning, Baltimore, Md.
Johnson & Johnson, New Brunswick, N.J.
Mead, Johnson & Co., Evansville, Ind.
Lederle Laboratories, Inc., 511 Fifth Avenue, New York, N.Y.
Eli Lilly & Co., Indianapolis, Ind.
Lloyd Brothers, Pharmacists, Inc., 300 West Court Street, Cincinnati, Ohio.
Magnus, Mabee & Reynard, Inc., 32 Cliff Street, New York, N.Y.
Mallinckrodt Chemical Works, 3600 North Second Street, St. Louis, Mo.
The Maltbie Chemical Co., 246–250 High Street, Newark, N.J.
The Maltine Co., 30 Vesey Street, New York, N.Y.
Maywood Chemical Works, Maywood, N.J.
Robert McNeil, 2900 North Seventeenth Street, Philadelphia, Pa.
Merck & Co., Inc., Rahway, N.J.
The Wm. S. Merrell Co., Cincinnati, Ohio.
Monsanto Chemical Works, 1724 South Second Street, St. Louis, Mo.
The National Drug Co., Inc., 4679 Stenton Avenue, Philadelphia, Pa.
Nelson, Baker & Co., 1301 West Lafayette Boulevard, Detroit, Mich.
The New York Quinine & Chemical Works, Inc., 99–117 North Eleventh Street, Brooklyn, N.Y.
The Norwich Pharmacal Co., Norwich, N.Y.
Parke, Davis & Co., Detroit, Mich.
The E. L. Patch Co., Stoneham Post Office, Boston, Mass.
S. B. Penick & Co., 132 Nassau Street, New York, N.Y.
Chas. Pfizer & Co., Inc., 81 Maiden Lane, New York, N.Y.
Pitman-Moore Co., 1220 Madison Avenue, Indianapolis, Ind.
Seabury & Johnson, 87 Maiden Lane, New York, N.Y.
G. D. Searle & Co., 4737 Ravenswood Avenue, Chicago, Ill.
Sharp & Dohme, Broad and Wallace Streets, Philadelphia, Pa.
G. H. Sherman, M.D., Inc., 14600 Jefferson Avenue, East, Detroit, Mich.
Smith, Kline & French Laboratories, 105 North Fifth Street, Philadelphia, Pa.
Upsher Smith Co., 529 South Seventh Street, Minneapolis, Minn.
E. R. Squibb & Sons, 745 Fifth Avenue, New York, N.Y.
Frederick Stearns & Co., Detroit, Mich.
R. J. Strasenburgh Co., 195 Exchange Street, Rochester, N.Y.
Tailby-Nason Co., 49 Amherst Street, Kendall Square Station, Boston, Mass.
The Tilden Co., New Lebanon, N.Y.
The Upjohn Co., 223 East Lovell Street, Kalamazoo, Mich.
Henry K. Wampole & Co., Inc., 440 Fairmount Avenue, Philadelphia, Pa.
Wm. R. Warner & Co., Inc., 113 West Eighteenth Street, New York, N.Y.
The Wilson Laboratories, 4221 South Western Avenue Boulevard, Chicago, Ill.
John Wyeth & Brother, Inc., 1118 Washington Avenue, Philadelphia, Pa.
The Zemmer Co., 3943–47 Sennott Street, Oakland Station, Pittsburgh, Pa.

LETTER OF JOHN A. NASH, ATTORNEY AT LAW, CHICAGO, ILL.

DECEMBER 18, 1933.

Hon. ROYAL S. COPELAND,
Chairman Senate Committee on Commerce,
Senate Office Building, Washington, D.C.

DEAR SENATOR: I represent a number of concerns which are selling through the mails preparations intended for the relief, alleviation, and cure of various diseases and disorders which afflict the human race. These are products within the classification of patent medicines and these clients of mine are all interested in the so-called Tugwell bill which, I understand, is properly entitled Senate bill 1944.

This office was represented at the hearing before the subcommittee when you presided and we were very greatly interested in the statements of the various witnesses. I understand that you have given permission to the various interests represented to submit suggestions or briefs for consideration by the full committee on or before December 20. I suppose most of the objections to the bill have been very well presented, but there are one or two things which occur to me because of the nature of part of my practice that I do not think have been enlarged upon and which might be of some service to the committee in considering its report on this bill.

I served in the Post Office Department as an assistant to the Solicitor for many years and we had many of these medical cases before us. In my practice I have been familiar with the work of the Federal Trade Commission, the Post Office Department, and of the Food and Drugs Administration of the Department, of Agriculture, and perhaps I am in a position, arising from my experience in the practice of law, to make some suggestions that may be worth while for the consideration of the committee in framing its recommendations on this bill.

May I call your attention, Senator, to the fact that this bill attempts to give powers to the Department of Agriculture which have been fairly exercised by another department and commission of the Government in a very fair and salutary manner for many years. The Department of Agriculture properly may deal with standards, ingredients, and adulteration of drugs and foods, but when it attempts to go beyond these limitations in an effort to obtain power to determine what shall be sent through the mails in the way of advertising, it seems to me that it is usurping the natural jurisdiction of the Post Office Department and the Federal Trade Commission. I have no doubt that the Department is aiming to remedy in a general law particular wrongs to the public, and its desire in this respect is commendatory. However, the proposed law is so broad in its terms that it brings the Department of Agriculture into a field which has been fairly and effectively covered, heretofore, for many years, by the Post Office Department and the Federal Trade Commission.

As you know, the Post Office Department has authority to issue so-called "fraud orders" against any individual or concern that the Postmaster General determines, upon evidence satisfactory to him, is engaged in obtaining money by means of false or fraudulent pretenses, representations, or promises. This law has been for many years very effectively and conscientiously enforced. It is true that it is necessary for the Post Office Department in issuing such orders to determine that the advertiser is not acting in good faith in making the representations which are charged to be false. This has not been a deterrent to the Department so far as the enforcement of this law is concerned. As any lawyer knows, the question of good faith is a matter of inference. Where a man makes statements that he should know are false, the natural inference is that they are not made in good faith.

In addition to this, the courts have held frequently that a man selling medicines or drugs for the relief or cure of disease is in the peculiar position of purporting to have knowledge of the effect on human beings of the drug which he sells. In other words, his position is quite distinct from that of the ordinary vendor of merchandise because thereapeutic claims, according to the decisions of the courts, carry with them the implied representation that the vendor thereof has peculiar knowledge of the value of the drugs or medicines which he is selling. This is the well-established doctrine of law upon which the Post Office Department can well rely in making its findings; and I believe that an examination of the records of the Post Office Department, in the so-called medical cases that have been before it, will show that it has not been embarrassed in any way in finding lack of good faith in the administration of the postal fraud law.

From my personal knowledge the personnel of the Post Office Department is such that its administration of the postal fraud law has been most effective so

far as these medical mail-order schemes are concerned. It is true that in some instances fraud orders have not been issued where, under the proposed law, the concern would be put out of business or criminal action taken, but the interest of the public has been well subserved by the requirement that all misrepresentation be abandoned or that the concern making them discontinue business. Why the Department of Agriculture would seek to exercise a surveillance over the mails, in view of the very efficient administration of the postal fraud law, is something I cannot comprehend. In addition to this, Senator, there is, as you know, a statute which makes it a criminal offense for any individual or concern to use the mails in the conduct of a scheme to defraud. Many convictions have been obtained in the Federal courts under this statute, which is a cognate statute with the postal fraud law.

I am calling these things to your attention, Senator, with the idea of asking you and your colleagues to bear in mind in your consideration of the proposed bill that there are already laws which adequately cover the offenses which are to be reached by this substitute for the Food and Drugs Act. I certainly think, from my experience both in the Government service and outside it, that some opinion should be sought from the Post Office Department as to the necessity for the enactment of a bill of this character. It probably will be said that the Post Office Department, in administering the law, must in order to prevent fraud determine that fraud is contemplated. The opinion of this office is that this is an entirely sensible requirement. To convict a man and send him to prison because of the fact that he inadvertently and in good faith makes statements that are not in accord with the general agreement of medical opinion seems to me far beyond any proper conception of justice and far outside of the general understanding of criminal acts in the United States. It goes far beyond constitutional ideas of the freedom of the press and far beyond the Anglo-Saxon conception of the liberty of the individual to puff his merchandise and attempt to sell it as better than that which is offered by others. To leave to the Secretary of Agriculture the determination of whether by ambiguity or inference a misleading impression is created by advertising is far beyond anything that has yet been attempted in American law. After all, these things rest upon the old conception of fraud and to put it into the power of one individual, whether a Government official or otherwise, to determine that a man is a liar or a law breaker because he speaks an opinion not in harmony with that of the majority of physicians, or what the Secretary of Agriculture determines is not that of a majority of physicians, is absolutely not harmonious with the trend of the decisions of the courts and of the general conception of legal principles. In this connection I would respectfully call your attention to *American School of Healing* v. *McAnulty*, 187 U.S. 194; *Post* v. *United States*, 135 Federal, 1; *U.S.* v. *Raladam Co.*, 283 U.S. 643.

I would respectfully also call your attention to the fact that the Federal Trade Commission has authority supported by decisions of the highest court in the land to prevent the making of false and deceptive representations in advertising and it has exercised this power fairly. May I call your attention to the case of *Sears Roebuck & Company* v. *Federal Trade Commission*, reported in 259 Federal, 307, and other cases of similar import. The Federal Trade Commission has ample authority to prevent the making of false or deceptive or misleading representations regarding drugs or medicines. May I respectfully suggest that the proposed law be submitted to the Federal Trade Commission for its recommendation?

In conclusion, let me say that the proposed law is objectionable and should not be enacted into law for the reasons that:

1. The jurisdiction which it seeks to enter is already adequately, fairly and properly covered by laws which empower both the Post Office Department and the Federal Trade Commission to prevent the abuses which the proposed laws seek to authorize the Department of Agriculture to deal with.

2. There is no necessity for the enlargement of the jurisdiction of the Department of Agriculture to cover advertising and any additional power that it may be deemed proper to give to the Department of Agriculture should be restricted to those powers which naturally may belong to it, covering the ingredients and the value thereof contained in package medication; it should not be empowered to go into the field of advertising, duplicating a control that is already exercised by the Post Office Department and the Federal Trade Commission, and giving to a personnel composed of physicians antagonistic in general to the sale of patent medicines a power that is now exercised by organizations not composed of physicians but largely of lawyers and men of general experience and feeling who are guided by principles of law and common sense that can not be ascribed to the medical profession as a whole.

In view of these suggestions, I respectfully submit that the committee should report the proposed bill unfavorably. If it decides that this should not be done, I would respectfully suggest that it eliminate from the proposed bill paragraph J of section 2, all of section 9, paragraphs 3 and 4 of Section 17 and all other provisions of the proposed law which contemplate giving to the Department of Agriculture the jurisdiction and the power over advertising which are now enjoyed and exercised by the Post Office Department and the Federal Trade Commission.

Respectfully submitted.

JOHN A. NASH.

BRIEF OF CHARLES T. STOUT, ON BEHALF OF THE DELSON CHEMICAL CO., INC.

The Delson Chemical Co., Inc., was incorporated in April 1915. It manufactures pharmaceuticals and chemicals for physicians and for veterinary practice. It specializes in pharmaceuticals compounded from pure drugs. It owns and operates processes for the improved manufacture of drugs, among which is the Delson process for refining medicinal creosote. This company has had many years experience in dealing with the Federal bureaus under the laws now on the statute books. It is the opinion of this company, formed after a careful study of the proposed measure and a survey of conditions, as revealed by its own contracts and experience, that Bill S. 1944 known as the "Tugwell Bill" will defeat the purposes for which it is inteded and is in itself fraught with danger to health and public welfare. This bill is unsound because:

(1) It legalizes the distribution of adulterated, deleterious, and poisonous drugs.

(2) It is unfair to the manufacturer and destructive of his property rights.

(3) It exploits the medical profession and the public.

(4) It places too great power in the hands of those who have neither the knowledge nor the facilities to properly enforce the law, and who have repeatedly abused the power granted to them in the past.

(5) It proposes to establish by law something that does not exist and which has been a constant source of disagreement in the past, "the general agreement of medical opinion."

(6) It is a restraint on the advancement of science.

(7) The proposed law is unenforcible even if supported by excessive appropriations.

In support of this opinion the following evidence is offered, accompanied by exhibits which have been filed with the Subcommittee of the United States Senate Committee on Commerce.

IT LEGALIZES ADULTERATED AND POISONOUS DRUGS

The bill accepts the standards of purity of the United States Pharmacopoeia. In the membership of the United States Pharmacopoeial Convention are the names of many members of firms of drug manufacturers representing the wholesale and retail drug trade in their national and State pharmaceutical associations. The standards for many of the drugs which these conventions have adopted are commercial standards, not standards of purity. Some of the drugs manufactured under these standards are very poisonous. If the manufacturers of pure drugs were permitted to freely advertise and distribute their products, poison drugs would be soon driven from the market, but special privileges are extended to manufacturers of official drugs. At the same time the full power of the Federal Government has been exerted to prevent the distribution of improved products which may interfere with the business of protected manufacturers. There are men in key positions in the Federal bureaus who have promoted the interest of favored manufacturers. Some of these key men are later found in the employ of the large drug manufacturers.

IT IS UNFAIR TO THE MANUFACTURER AND DESTRUCTIVE OF HIS PROPERTY RIGHTS

The bill (S. 1944) provides for the disclosure of formulas which carry, in many instances, good will values which have accrued over a period of years. The manufacturer of pharmaceuticals has come to rely upon the secret formula for the protection of his rights, for the reason that the Federal bureaus may contest the validity of patents granted by the Patent Office, subjecting the holder to expensive litigation; trade-marked names may be granted to competitors if a way is found of slightly varying the spelling—as in the case of one of our products substituting "ph" for "f." If the manufacturer of a reliable products is forced to disclose his formulas he may find his products in competition with cheap imitations compounded with poisonous U.S.P. drugs that will be sold as "just as good," which will eventually ruin the reputation of his formulas, and may even reflect on the reliability of the drugs of which they are composed.

IT EXPLOITS THE MEDICAL PROFESSION AND THE PUBLIC

Because of public faith in the symbol U.S.P. it has been pcssible to market official imitations of pure drugs under this symbol. The following is an example: In the list of pharmaceuticals which this company manufactures are products containing pure beechwood creosote. The creosotes of the Pharmacopoeia are distilled from the tars of mixed hardwoods. The standard for creosote specifies 90 percent purity, the standard for creosote carbonate 85 percent purity. A patent (No. 1199271) has been granted for the manufacture of "beechwood creosote" from the tar oils obtained from "hardwood" tar. The Food and Drug Administration has taken the stand that there is no difference between these creosotes. The unregulated 10 percent of creosote U.S.P. may, if distilled at too low a temperature, contain phenol (carbolic acid). Phenol is one of the most deadly and rapidly acting poisons known. A 2½-percent solution of phenol applied to the surface of the body may produce serious injury, subacute phenol poisoning has occurred by its absorption from surgical dressings. If the 10 percent unregulated portion of creosote U.S.P. is distilled at too high a temperature it will contain coerulignol, a deadly poison, a drop of which placed on the tongue will cause bleeding. Many attempts have been made to obtain a revision of the creosote standards of the Pharmacopoeia, notably suggested changes by L. Wallis Gibbons (exhibit 1), before the tenth revision. What happens when these poisons reach the internal organs? The death rate in diseases like pneumonia tells the story. The mortality in pneumonia treated with pure beechwood creosote carbonate is less than 5 percent as demonstrated by careful investigators (exhibits 2 and 3) as compared with the normal death rate of about 25 percent. Since the adulteration of the drug, even the medical textbooks are uncertain of the value of creosote in this disease.

There can be no greater exploitation of the public than to levy taxes, on the plea of public health, to support a system which permits the official substitution of an imitation for a drug that is used in cases of life and death. In the case of the physician it may cost him the life of a paying patient, or the confidence of the people who make up his practice. For no physician can give reliable service if the drugs he prescribes are unreliable.

IT PLACES TOO GREAT POWER IN THE HANDS OF THOSE WHO HAVE NEITHER THE KNOWLEDGE NOR THE FACILITIES TO PROPERLY ENFORCE THE LAW

The Federal Food and Drug Administration has neither the knowledge nor the facilities to enforce the law. It has been the practice of Government Bureaus to look for outside help from universities supporting medical colleges and other institutions of similar character. Information obtained from these sources may or may not be reliable. In 1918 at a time of national emergency (the influenza pandemic) this company offered its pure beechwood creosote carbonate to the United States Government. The product was sent to a medical college and a false report was made of its medicinal value. It developed years afterward that the report was handled by one who holds a high position with a competitor, a well-known drug firm (exhibits 4 and 5). This company now has evidence of four false reports of its products made by or for the Government.

The results obtained with our pure beechwood creosote as compared to the mortality in diseases where the adulterated official creosote was prescribed began to call attention to the quality of the drugs that were permitted in distribution. An effort was made to prevent the advertising of our pure products. A complaint, by an unknown complainant, was filed with the Federal Trade Commission and information from which false charges were manufactured was supplied to the Commission by the Food and Drug Administration. The Federal Trade Commission charged unfair methods of competition, in advertising our pure beechwood creosote products, giving as the reason "that creosote, the basic ingredient of Delson Chemical Co.'s products, has no antiseptic effect upon the digestive organs, nor has it been proven to be an effective therapeutic agent in any respect."

Creosote has been used medicinally for more than 100 years. It is recognized in the pharmacopoeias of every civilized nation. No objection was raised by the

Federal bureaus against advertising and selling an adulterated creosote. It was only when a pure creosote came in competition with the adulterated drug that an effort was made to restrict its distribution. Hearings were held in Washington, D.C., New York City and Columbus, Ohio, where the witnesses to be heard resided. Evidence for the Government was supplied by the Federal Food and Drug Administration. The testimony covered 419 pages. This testimony, made under oath, disclosed that the charges were based on a false and fraudulent test of our product. There is some evidence that the product was tampered with before testing. The official of the Federal Food and Drug Administration, in charge of the test, testified that he had held this position for 5 years, during which time approximately 8,000 preparations had been examined. On cross-examination it developed that he did not know the common principles of common drugs (exhibit 6). He testified that the Department did not have any inspection system of food or drugs. What work was done depends "entirely upon the activities of the Food and Drug Administration according to the funds they have available."

To establish commercial competition the names of seven firms were introduced as being in competition with this company. Six of these firms were advertising and selling their products in violation of the rulings of the Federal Food and Drug Administration. The medical director of one of these firms admitted that this was done with the "passive consent" of the Administration. The examiner for the Federal Trade Commission ruled that there was no relevancy to the issues in the case whether or not other manufacturers were violating the law. In other words, a reputable manufacturer selling pure drugs may be put to great expense defending false charges sustained by false evidence, because he is in competition with manufacturers who, although they are violating the law, have been able to obtain illegal assistance from the Food and Drug Administration.

Much has been made of the so-called "chamber of horrors", an exhibit of patent-medicine preparations collected by the Food and Drug Administration as examples of law violation. On June 24, 1930, Walter G. Campbell, Director of Regulatory Work, United States Department of Agriculture, appearing before the United States Senate Committee on Agriculture and Forestry admitted, because of limited funds, the Bureau was obliged to "make some decision with respect to how they can be employed most effectively in the protection of the health and the pocketbook of the public." The Administration was permitting some firms, because of their "reliability", to utilize substandard drugs for the manufacture of standardized products. Senator Wheeler, at the hearing above referred to, criticized the conduct of the Administration, "If the Congress of the United States could not pass that law by reason of the fact that it would be class legislation, then it cannot delegate to the Secretary of the Treasury, the Secretary of Agriculture, or to any other governmental agency, a power that it does not itself possess. That is just simply elementary". We now find these same "reliable" firms manufacturing products for our competitors who are selling these products in violation of the Department's rulings with the passive consent of the Department. If special privilege is extended to "reliable" manufacturers to violate the law, others may follow their example.

The purity of drugs involves technical questions that only those with the knowledge of chemistry and medicine can pass on. There are, however, legal questions here with which every layman is familiar. The laws against false witness are as old as the Tablets of Moses. False evidence has been presented, attorneys for the Food and Drug Administration and the Federal Trade Commission have falsified evidence in their briefs. Decisions of the United States courts have been disregarded. We felt that our company was protected from bureaucratic aggression under decisions of the United States courts. On October 12, 1932, we wrote to the Department of Justice:

"We feel that we are entitled to know whether these decisions of the United States courts can be depended on. If they are so doubtful that they cannot be enforced, or if there is unwillingness on the part of the Government to enforce them against the bureaus, we believe we should be so informed."

We finally received the following answer on November 14, 1933:

"We wish to inform you that the Attorney General is permitted by statute to give opinions only to the President and the heads of the executive departments" (exhibit 7).

With this evidence before us we believe it would be unsafe to intrust greater powers to the Federal bureaus.

IT PROPOSES TO ESTABLISH BY LAW SOMETHING THAT DOES NOT EXIST—"THE GENERAL AGREEMENT OF MEDICAL OPINION"

In a science that has advanced as rapidly as medicine has in recent years, it would seem the height of presumption to attempt to rely upon the "general agreement of medical opinion", which is constantly changing. It must also be remembered that changes in opinion do not always make for progress. Knowledge gained from mistaken opinions eventually results in the selection of the things of value and discarding the undesirable. Many foolish laws have been based on mistaken medical opinion, as for example, the Boston statute which prohibited taking a bath except with the advice and consent of a physician. It must be apparent to all that there can be no reliable concensus of medical opinion if the drugs the physician uses are unreliable. The hearings before the Committee on Agriculture and Forestry of the United States Senate, February 12 to June 30, 1930, disclosed that many valuable drugs were being adulterated. Nineteen hundred and eighty-two pages of testimony were taken, and printed by the Government Printing Office. The hearings showed that the Federal Food and Drugs Act was not being enforced, and that many deaths and injuries were resulting from the distribution of adulterated drugs. Before we can have reliable medical opinion we must have reliable remedies to base them on. To make sure that remedies will be reliable we must have simple, understandable laws that can be enforced, and that will not give discretion which may be abused.

IT IS A RESTRAINT ON THE ADVANCEMENT OF SCIENCE

Compare the position of medicine today with that of other sciences. Note some of the great achievements of mankind in other fields of human endeavor. Consider only the most recent successes. Man is able to talk over a wire from New York to San Francisco and recognize his friend's voice. He has encircled the globe through the air in more than one form of man-made machine. He has harnessed the air waves to carry his messages, his voice and his pictures, flashed by wireless, from one country to another. Curative medicine, on the other hand, if we accept section 9 of the proposed bill, in spite of all we have learned about disease, stands almost exactly where it did at the beginning of the Christian Era. Among the diseases mentioned in section 9, for which "self-medication may be especially dangerous, or patently contrary to the interests of public health", are some in which the most successful research work has been done in recent years. In many of these diseases, early treatment is of great importance, and it is impossible to inform the public without mentioning these diseases by name. For example, pneumonia should be prevented by the proper treatment of the cold or bronchitis which may lead to this disease.

This form of obsolete legislation has been pushed in municipal, State, and National legislatures by lobbyists in the interest of manufacturers of obsolete remedies. Too often the health officer, with the responsibility of a community's welfare on his hands, will give aid to the medical lobbyist if he can be persuaded that his act is for the benefit of the community or his profession. We give as an example, exhibit 8. Information had come to us that certain lobbying against our products was being carried on. A test advertisement was placed in the Morning Oregonian, of Portland, Oreg., based on research work that had been done in a board of health hospital of a large Eastern city. This work was supported by clinical charts and a sworn affidavit from the hospital authorities. It was not long before we received the letter marked "Exhibit 8".

The Oregonian also received a letter from this eastern official requesting this western paper "to carefully censure future publicity." Here is a case of the department of health of a city supported by taxpayers' money attempting to suppress the publication in Portland, Oreg., of successful research work carried on in its hospitals. We ask the Congress to consider carefully whether this bill is offered in the interest of the public, or for the protection of certain vested interests, whose methods of treating disease have become obsolete.

THE PROPOSED LAW IS UNENFORCIBLE EVEN IF SUPPORTED BY EXCESSIVE APPROPRIATIONS

A study of the Tugwell bill discloses that the problems connected with enforcement have been ignored. Since the passage of the Volstead Act, the country has been awake to the dangers of unenforcible legislation. It requires more than the enactment of a statute to establish a workable law. There are clauses in bill S. 1944 which are contrary to the decisions of the United States courts and the

opinion of the Solicitor General. The nonenforcement of the Volstead Act and the corruption that followed may be attributed in some measure to lack of the necessary appropriations for the enforcement of the law. The Volstead Act dealt with one drug, alcohol. The proposed law deals with not only every drug in the Pharmacopœia and every combination and compound of drugs, but it proposes to cover foods and cosmetics as well. Walter G. Campbell has repeatedly called attention to the lack of funds for the enforcement of the old law, and has offered this as an excuse for permitted violations. With the added burdens of supervision of advertising, factory inspection and regulation, etc., is there any hope that there will ever be sufficient funds available for efficient enforcement under the proposed bill?

The country is still faced with problems of the depression, one of the major causes of which has been the economic waste brought about by ill-considered legislation which must be supported by taxation. In addition to the taxes themselves, under our present system of raising revenue, there is the heavy expense in clerical salaries for keeping records and preparing schedules made necessary under many of our laws. For many manufacturers this is a greater burden than the taxes actually paid. In laws where the administrators are given discretionary authority there is always the additional expense of legal advice or the still more expensive method of obtaining the "passive consent" of the administration. With all these difficulties of enforcement the Congress is offered a bill which, if it is enacted, will do nothing more than legalize the distribution of the adulterated drugs of the United States Pharmacopœia.

CHARLES T. STOUT, *President.*

DECEMBER 23, 1933.

BRIEF OF ELISHA HANSON, OF WASHINGTON, D.C., ON BEHALF OF THE AMERICAN NEWSPAPER PUBLISHERS ASSOCIATION

Now comes the American Newspaper Publishers Association, by Elisha Hanson, its attorney, and submits for the consideration of Congress, and more particularly for the consideration of the members of the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Commerce of the Senate, its views on H.R. 6110 and S. 1944. The sections of the measures referred to for purposes of convenience will be those of S. 1944.

OPPOSED TO FALSE ADVERTISING

The interest of the association is not that of a manufacturer or distributor of articles coming within the purview of these measures. The membership of the association is confined to publishers of daily and/or Sunday newspapers. Daily and Sunday newspapers comprise the most extensively used advertising medium in the United States. So, naturally, any measure which affects advertising is of vital interest to publishers of daily newspapers. In order that there may be no misunderstanding as to their position, however, it is stated without equivocation that this association does not approve of false or fraudulent advertising. It wants none of it. And for more than 40 years its membership has constantly and unflinchingly opposed false and fraudulent advertising.

On the other hand, it should also be stated, and is so stated, that the association is opposed to this measure, in its present form, for reasons which will hereinafter be given.

Assuming, for the purpose of argument, that the present Federal Food and Drugs Act should be strengthened, the question arises as to why a sincere effort is not made to plug the gaps in it rather than to rewrite it completely. Surely the years of experience under that law, together with the weight and value to be given judicial action thereunder, have not indicated its complete futility. However, this association does not care to discuss either the merits or the weaknesses of the act, the value or lack of value of products which come under its provisions or those of the pending measures. Rather, it will confine its discussion entirely to matters of procedure, which directly affect its membership.

This measure proposes that an unjustified and unwarranted responsibility be attached to publishers with respect to the representations contained in advertisements printed in their newspapers.

Under existing Federal law, the responsibility of publishers for advertisements appearing in their publications is specifically limited. The postal laws provide

that all advertising matter shall be clearly identified as such and with respect to paid reading matter that it be specifically marked as an advertisement. The Securities Act follows the postal laws, except that in the case of paid reading matter, the name of the advertiser and the amount paid for the advertisement must be printed simultaneously with and as a part of the advertisement.

Section 17 (a)-(3) and (4) of this measure, however, makes the publisher responsible for the dissemination of any false advertisement which may appear in his columns. Further, other sections of the measure contain not only a new definition of false advertising and a hitherto unheard of method of determining whether or not an advertisement is false.

Section 17 (b) fixes penalties, of both fine and imprisonment, for violations of paragraph (a).

These paragraphs must be distinguished from section 17 (c), which provides heavier penalties for willful violators than for innocent persons, as covered in sections 17 (a) and (b).

This association has no objection to the fixing of any penalty, however great, for the willful distribution or dissemination of false advertising of foods, drugs, cosmetics, or any other product in any way injurious to the public welfare.

UNREASONABLE PENALTIES SOUGHT

It insists, however, that there is neither reason nor justification for the penalties provided for in section 17 (b) when and where the publisher is ignorant of the falsity of the advertising, especially when the untruth or misrepresentation is a subject for later determination by an executive branch of the Government, from the findings of which no appeal to the courts is provided.

If it be the purpose of the sponsors of this bill to prohibit the advertising of all food products, as well as all drugs and cosmetics, of whatever kind or description, the enactment of sections 17 (a) and (b) will accomplish it, for under those prohibitions and penalties no publisher would dare to accept an advertisement of any article which comes within the scope of the measure.

Equally, if not more, vicious, insofar as its application to the press is concerned, is section 19. Under this section, it would be possible to suppress any newspaper in this country on an allegation that it is guilty of the repetitious dissemination of false advertising of any food, drug, or cosmetic. Advocates of the measure may say this view is fantastic, but the author of the bill has specifically written into this section the provision that "in such injunction proceedings it shall not be necessary to show on the part of such person an intent to continue such nuisance." Further, it must be recognized that when an equity court takes jurisdiction, its power is unlimited.

The advertisement being an integral part of the newspaper printing it, this power of injunction, as this section is written, gives an unlimited power of suppression. Of course, insofar as newspapers are concerned, the section is in direct conflict with the first amendment to the Constitution of the United States, which provides that Congress shall pass no law abridging the freedom of the press.

In the foregoing discussion, the terms "false advertisement" and "false advertising" are used not per se but as defined by the proposed act. It is important that the truth or falsity of an advertisement is a matter left to the sole determination of the Secretary of Agriculture, from whose finding of fact there is no appeal. It is even more pertinent to reiterate that the penalties of fine, imprisonment, and suppression may be inflicted upon a newspaper publisher entirely innocent of any willful intent, and for the printing of an advertisement about which there was no question at the time it was offered. In other words, the Secretary can make an ex post facto finding and then proceed against a publisher or his publication, or both.

The arbitrary and capricious character of such provisions is indicated by reference to section 9 (a), which says:

"An advertisement * * * shall be deemed to be false if in any particular it is untrue, *or by ambiguity or inference creates a misleading impression* * * *" (Italics supplied.)

To place such broad powers of determination in any individual, without the right of appeal, is unthinkable. To provide, as does this measure, ex post facto penalties, including that of suppression, for pzrsons entirely innocent of any intent to violate the law is even more unthinkable. It is not only unwarranted and unjustified but un-American. Surely the Congress will not countenance such a preposterous proposal.

There can be no doubt that the sponsors of this measure seek to remove, insofar as possible, from the Federal courts all jurisdiction over food, drugs,

and cosmetics and place it within a bureau of the Department of Agriculture. The present Chief of Food and Drug Administration of the Department, in a series of radio talks in the period of the National Farm and Home hour in September, October, and November complained of the failure of the courts to uphold many of his Bureau's contentions.

HOW SUCH REGULATION SOMETIMES FUNCTIONS

Just to illustrate how bureaus of the Department of Agriculture function when not subjected to judicial review, your attention is called to the record of the hearing held on October 31, 1929, in the matter of the Asiatic and Japanese beetle quarantine enforced by the Plant Quarantine and Control Administration of that Department. This record discloses the outrageous fact that, after prescribing regulations for the conduct of business of nurseries within quarantined areas, the Department would not permit plants to be shipped from any such nursery unless bugs or grubs, introduced into the soil of the nursery by the Department's own agents, were killed by the treatment prescribed by the Department. In other words, under the terms of that regulation, if the Department suspected a nursery of being infected, but was unable to prove it, it would introduce the pests onto the premises, prescribe a treatment, supervise the giving thereof, and then, if its own bugs were not killed by its own formulas, refuse its approval for that nursery to make any shipments.

In order to grow the grubs the Department maintained a special laboratory for their propagation. Further, the record disclosed that as the Department became more adept in growing the pests, they, in turn, became more difficult to kill, and over a period of 3 years the poison formulas were changed five times, with the result that, in 1929, the formula then in use, even though it might not be wholly efficacious in destroying the Department's specially propagated pests, invariably destroyed all plant or vegetable life with which it came in contact.

Fortunately, there came a Secretary of Agriculture who, after a review, rescinded that regulation, but the important fact is that it had been enforced for more than 3 years before he acted, notwithstanding earnest and urgent protests of the nurserymen injured by it throughout that period.

With a record such as that of the quarantine regulation just referred to back of it, no administrative agency of the Government should be given such broad powers as are proposed in this act without the safeguard of a prompt judicial review, both as to fact and law.

EXISTING LAW ADEQUATE

Insofar as false and fraudulent advertising are concerned, it is pertinent to point out that there is ample authority in existing law to take care of all offenders. The postal statutes provide for both fine and imprisonment for persons who use the mails to obtain money on the basis of any false or fraudulent representations. The Federal Trade Commission Act provides for a cease and desist order where such advertising injures a competitor. The query naturally presents itself as to why the Food and Drugs Administration has not availed itself of these statutes, if its own law is insufficient to meet certain exigencies. Until by actual experience and test they have proved inadequate, no further grant of power should be made.

In conclusion, this association is not opposed to any proper amendment of the Federal Food and Drugs Act in the public interest; it is not opposed to proper and adequate penalties for willful violators of the law. It does oppose the proposal to give the Department of Agriculture the broad powers included in the bill; it opposes making the Department the final arbiter in matters of fact; it opposes penalties on innocent persons; it opposes ex post facto penalties; it opposes the specific power to suppress a newspaper, even though it does not intend to offend or continue to offend.

Further, in the present form of the bill, it is opposed to the whole measure.

BRIEF OF HON. THOMAS B. LOVE, OF DALLAS, TEX., ATTORNEY FOR CRAZY WATER CO. OF MINERAL WELLS, TEX.

This brief is submitted in support of two proposed amendments to S. 1944, copies of which are attached, and will be referred to as no. 1 and no. 2, respectively.

I am proposing these amendments and submitting this brief in support of them, as counsel for the Crazy Water Co., owners of the Crazy Wells of Texas, located at Mineral Wells and elsewhere in that State.

The Crazy Wells are among the original, and are probably the best known of the group of mineral water wells located at the city of Mineral Wells, Tex., which have served the people as a great health resort for more than half a century, or, to be exact, since the discovery of the original Crazy Well in 1879. The latest edition of the Encyclopedia Brittanica, speaking of "Mineral Wells, Tex.," says:

"It is primarily a health and pleasure resort. More than 150,000 visitors come annually to drink its water and take the baths."

Crazy Crystals, consisting of salts derived from evaporating the water of the Crazy Wells, dissolved in ordinary drinking water will substantially reproduce the mineral water produced by the wells. These crystals are of the same class, and largely of the same chemical composition and therapeutic utility, as the salts of the famous Carlsbad and other waters of Europe, including the Government-owned Montecatini Springs of Italy, which are widely sold in this country, being admitted free of duty by express provision in our tariff laws, paragraph 1718, which adds to the free list:

"Mineral salts obtained by evaporation of mineral waters, when accompanied by duly authenticated certificate and satisfactory brief showing that they are in no way artificially prepared and are only the product of a designated mineral spring."

These Crazy Crystals have been produced and sold for more than a quarter of a century; and, in recent years, they have come to be used by millions of the American people, being sold and distributed in every State of the Union.

Proposed amendment no. 1 reads as follows:

Amend S. 1944 by adding, at an appropriate place, the following:

"*Provided*, That it shall not be unlawful to disseminate, through the label or otherwise, truthful information or sincere and reasonable expressions of opinion relative to the remedial or health-promoting properties, or hygienic or therapeutic values of naturally produced mineral waters or salts derived from their evaporation".

The design and effect of this amendment is to prescribe and apply the simple tests of truth and sincerity, within the limits of reason, to the advocacy of the use of drinking water by the people.

It is respectfully submitted that, whatever harm may result from the sale, through the direct or implied misrepresentation of the therapeutic use and values, of synthetically produced drugs and medicines, no harm has ever resulted, or is likely to result from the misrepresentation of the remedial or therapeutic effect of naturally produced mineral waters.

There is nothing experimental in the use of mineral waters by the people for hygienic or health-promoting purposes. Certainly the great mineral water industry, with its springs and wells in New York, Georgia, Arkansas, Texas, Michigan, Wisconsin, and numerous other states, cannot be charged with using the American people as "100,000,000 guinea pigs."

There are few things in American life, or in human life, that are older—that are more time-tried—than the use of mineral waters for health purposes. The Encyclopedia Americana tells us:

"Mineral waters have been used as remedial agents from the earliest days of Greece and Rome. There were sulphureous thermal springs at Tiberius, which are still used by invalids from all parts of Syria in cases of tumor, rheumatism, gout, and other diseases. There are also warm springs at Calirrhoe, near the Red Sea, which are mentioned by Josephus as having been tried by Herod in his sickness. The Romans discovered the thermal springs in Italy and the springs in other parts of Europe; Baden, Aix, la Chapell, the Spa in Belgium, and others.

"Pliny mentions mineral springs in various parts of Europe."

And the same authority says:

"In the United States the Rock Spring was known at Saratoga, N.Y., among the Indians as early as 1767, and over 40 springs have since been discovered there. In 1830 springs were well and popularly known in West Virginia, and of these the Bath Mineral Springs were visited as early as 1777, while the White Sulphur Springs were used by the Indians in 1778."

and speaking of these so-called "bitter waters" the same authority says:

"The chief contents of these waters are the sulphates of magnesia and soda."

Certainly mineral waters ought not to be placed in any category of harmful and dangerous drugs of fake nostrums. It has grown to be a great American industry; and this growth has been under the leadership of the Nation and of numerous States.

Since 1840 the Government of the United States has owned and operated the great Hot Springs of Arkansas for the therapeutic and hygienic use both internally and externally of their waters by the people; and the State of New York owns and operates the great Saratoga Springs and promotes in all proper ways the internal and external use of their waters at the springs, and, as well, their sale for use in the homes of the people.

There are other States of the Union owning and operating mineral springs of which, we are authoritatively told, there are approximately 10,000 in the United States.

The Crazy Water Co. alone employs constantly, in producing and distributing its products, several thousand men and women scattered throughout the States of the Union.

Proposed amendment no. 2 reads as follows:

Amend S. 1944 by adding at the end of section 21, on page 29, the following:

"*Provided*, That no information as to any such judgment, decree or order, or proceedings or seizure, shall be disseminated more than 1 year after the date thereof, unless in response to specific requests for copies of the record thereof."

It would seem obvious that no useful purpose can be subserved by the dissemination by the Government of old, stale judgments affecting the reputation and business of a person or firm which is no longer violating any law or even the proprieties.

All of which is respectfully submitted.

THOS. B. LOVE,
Counsel for the Crazy Water Co.,
of Mineral Wells, Tex.

LETTER OF B. K. FISK, BOSTON, MASS., COUNSEL FOR UNITED DRUG CO., WITH SUGGESTED AMENDMENTS

DECEMBER 11, 1933.

Senator ROYAL S. COPELAND,
Chairman of the Committee on Commerce,
United States Senate, Washington, D.C.

MY DEAR SENATOR: I have prepared with some degree of care some sections to provide in the pending food and drugs bill, S. 1944, for a right of review. Copies you will find enclosed with this letter.

Occasionally we find prosecutors who think much more of scoring a big record of successful prosecutions than they think of justice to the prosecuted. Food and drug cases are especially conducive to such an attitude because their prosecutor can nearly always arouse the interest of nearly every person in the entire Nation.

The present bill would create an ideal situation for a publicity seeking zealot. He could both prosecute with zeal and, as a finder of the facts, grant himself successful results on short measures of proof, supplemented by large measures of prejudice.

Men who have long served as criminal prosecutors rarely make good criminal judges, because they acquire habits of thought which are not considerate of defendants.

It seems desirable to provide for a complete change of venue for getting entirely into a new atmosphere where review proceedings may be conducted.

It is desirable to have a board, or entire commission, conduct review proceedings.

The plan of having the appellate tribunal supplement its own record, wherever additional facts need development, is borrowed, in substance from New Jersey's appellate procedure, for its courts.

The plan of letting the Commission decide whether to review a case is suggested by United States Supreme Court practice. It would help to hold down the number of meritless appeals.

Copies of this letter, and of the enclosure, are being mailed to Mr. Campbell.

Yours very truly,

BRENTON K. FISK, *Counsel.*

It is suggested that the following sections should be inserted between sections 23 and 24 in Senate bill no. 1944, on food and drug regulation:

REVIEW PROCEEDINGS

SEC. 23-1. Any person who has sustained, or probably will sustain, substantial injury from any finding, determination, rule, or order of the Secretary of Agriculture, promulgated hereunder, may petition the Federal Trade Commission for review, and if it shall appear that his injury is, or probably will be, substantial and that there is, or probably may be, serious doubt of the soundness of the finding, determination, rule, or order of which such review is sought, it shall be the duty of the Commission to grant such review. In any event, the Commission shall, as soon as practicable, enter an order granting or refusing the petition.

SEC. 23-2. Upon the making of an order granting a petition for review the entire record, including all evidence and proceedings, whereon the action of the Secretary of Agriculture depended in making his finding, determination, rule, or order, shall become fully and freely available to the Commission, and shall be a part of its own record in the proceeding, with such validity and effect as if the Commission itself had duly created the same. Nevertheless the Commission shall have power and authority to provide, by just rules, for additional copies of the Secretary's record, or any parts thereof, to be filed with it by the petitioner in such form as the Commission may prescribe.

SEC. 23-3. Subject to the provisions of this statute, the proceedings before the Commission on such review shall be conducted in the same manner, and with the same authority and power, as cases duly instituted and prosecuted by the Commission under the Federal Trade Commission Act; and the Commission shall have power and authority to obtain any and all such new or additional evidence in the case as it shall deem necessary for a just and proper determination.

SEC. 23-4. Upon the filing of a petition for review, and until disposition thereof, and of any review which may be granted thereon, the Commission shall have power and authority, upon such terms as it may deem just, to suspend, in whole or in part, or to modify, or limit, any finding, determination, rule, or order of the Secretary in respect to which review is being sought; but except (a) to the extent to which they may be thus suspended, modified, or limited, by due order, or (b) to whatever extent they may be superseded, as hereinafter provided, all such findings, determinations, rules, and orders shall, at all times, be and remain in full force and effect.

SEC. 23-5. The Commission shall expedite the determination of all such review proceedings undertaken by it, and shall dispose thereof either by concurring with the Secretary, or by making its own findings, determinations, rules, and orders, which shall supersede those of the Secretary, and have force and effect as if originally made by him, together with force and effect as proceedings of the Commission, as if they had been duly made pursuant to the Federal Trade Commission Act.

SEC. 23-6. The Commission is charged with the duty, and is hereby granted power and authority, to make adequate provision, from time to time, by rules and regulations for the due and orderly exercise of the powers and responsibilities herein placed upon it.

Dr. William C. Woodward, director of the bureau of legal medicine and legislation of the American Medical Association, submitted the following analysis:

In many places in S. 1944 the Secretary of Agriculture is authorized to hold hearings. See particularly, section 23 (b) and (c), but also many other places in the bill. In one obscure passage, section 23 (b), the Secretary is given authority to exercise the powers and authorities vested in the Federal Trade Commission, which seems to authorize him to subpena persons and papers from any part of the United States to any other place, although the citation in the bill seems to be erroneous if it is intended to accomplish that end. Moreover, the Secretary is authorized to exercise any and all of the vast authority thus vested in him through any officer or employee whom he may designate for that purpose. And finally, and most remarkable of all, the findings of fact "by the Secretary shall be conclusive if in accordance with law." All this represents a proposed grant of authority unequaled by that of any court in the United States or by any administrative officer or board. The officer who is to execute the law is to make such regulations as he sees fit to enable him to do so and then is to decide on all questions of fact, if he sees fit to give a hearing before referring the case to the courts.

It is true that the finding of fact must be in accordance with law. That means only that if the person prosecuted can prove that the Secretary made his finding because of malice, caprice, or prejudice, his finding of fact can be set aside, but the burden of proof is on the defendant.

The Secretary is under no obligation to notify a person whose conduct is being inquired into that a hearing is to be held or to afford him an opportunity to appear and to defend himself. A person whose conduct is being inquired into may reside at a place so remote from the hearing that it is impracticable to appear even if he is notified. A person whose conduct is being inquired into has no right to challenge the intelligence, impartiality, and integrity of the officer who is to hold the hearing. He has no right to demand before the hearing the names of the witnesses who are to appear against him. He has no right to submit his own list of witnesses and to demand that they be subpenaed. He has no right to demand that the ordinary rules of evidence be followed or even approximated, nor has he any right to a certified copy of the proceedings in order that he may be able to show the court the unfairness of the hearing. He has no right to cross-examine witnesses. Nor has he, since probably all such hearings will be held by inferior officers and employees of the Secretary, an opportunity to be heard by the Secretary himself before the Secretary approves the findings of his subordinate and thus makes them his own within the meaning of the law.

To pretend that there is evidence of injury from adulterated, misbranded, and falsely advertised foods, drugs, and cosmetics that can be cured only by such a curtailment of the liberties of the people as is proposed by these provisions of this bill is certainly unjustified.

AUTHORITY TO FIX STANDARDS AND TOLERANCES DELEGATED

S. 1944 proposes to deprive the Secretary of the Treasury and the Secretary of Commerce of such authority as they now have with respect to the fixing of standards and of tolerances with respect to foods and drugs and to vest all such authority in the Secretary of Agriculture, moreover, while such standards as may now be established by the regulatory board are advisory only, the standards which it is proposed to authorize the Secretary of Agriculture to establish are to have the force and effect of law.

There is, however, nothing in the bill that is designed to insure the fitness of successive Secretaries of Agriculture for the discharge of this duty. It may be assumed that any Secretary of Agriculture will be fully qualified to speak with respect to standards and tolerances for stock feeds and possibly even with respect to standards and tolerances for medicines for domestic farm animals. His office in itself implies such qualifications. But with respect to fitness to speak with reference to the many problems of human health that are involved in the pending bill and with respect to the many industrial and trade problems likewise involved, the office of Secretary of Agriculture implies no such fitness. The Secretary may of may not be fit. The present law recognizes this situation when it gives joint authority to the Secretary of the Treasury and the Secretary of Commerce.

The Secretary of the Treasury has serving under him that agency of the Government lawfully authorized to speak with respect to human health, the Public Health Service. He has certain supervision, too, over foreign commerce, through the Custom Service. The Secretary of Commerce, through the several bureaus under him, is in touch with industry and trade, both foreign and domestic. There seems to be no reason for depriving them of their authority with respect to such matters when it comes to enforcing a food and drugs act. The public and the interests they represent are entitled to have them remain on any administrative legislative agency that may be set up under this bill, either to promulgate standards and tolerances or to promulgate rules and regulations having the force and effect of law. Whether standards and tolerances are or are not promulgated in the form of rules and regulations, with all the safeguards that have been proposed to safeguard the rights of the people and interested parties in the process, is possibly not a matter of great moment. If however, it be deemed best to promulgate standards and tolerances in any other way, then certainly, nevertheless, those same safeguards should be retained—notice, public hearing after reasonable notice, publication in a definite way, and the expiration of a stated period after publication before the standards and tolerances take effect.

Probably in the determination of standards and tolerances expert investigation should precede action by the nontechnically informed board authorized to promulgate rules and regulations. Such a board might well be made up of a competent member of the National Institute of Health, now a part of the Public Health Service, representing public health interests; a competent representative

of the Bureau of Standards, in the Department of Commerce, representing industrial and trade interests in a technical way; and some proper person from the Department of Agriculture, representing live stock interests and law administration. Such a board, vested with power to subpena persons and papers could certainly arrive at proper standards and tolerances than could the three secretaries of whom the legislative board is now composed or any other similar board.

A board such as is suggested or a similar board, possibly enlarged, vested with power to subpena persons and papers, would seem to be a more nearly proper agency to fix drug standards than the agency now vested with that authority. In fact, the present method seems to be not only of questionable expediency but of questionable legality.

S. 1944 proposes to continue the plan in force under the present law, of adopting the standards of the United States Pharmacopœia and the National Formulary as official standards. It proposes to go further, however. It proposes to adopt as official standards any standards that may be fixed in supplements to the Pharmacopœia and Formulary and at the same time to permit the Secretary to adopt methods of assay different from those laid down in the books named, in determining whether any given specimen or any drug does or does not conform to pharmacopœial and formulary standards. Here we have three independent agencies authorized to formulate standards and methods of assay, with no clear line of demarcation among them.

The inconvenience liable to arise from such a situation is apparent. But a serious question arises with respect to its legality, for the United States Pharmacopœia is not a Government publication as is sometimes supposed, nor is the National Formulary. The Pharmacopœia is published under direction of the United States Pharmacopœial Convention, which is assembled once every 10 years, and under the immediate supervision of its board of trustees. The National Formulary is published under the direction of the American Pharmaceutical Association. Until recently no supplements to these books were published to keep them up to date, but some plan has recently been adopted whereby that end is expected to be accomplished.

The United States Pharmacopœial Convention and the American Pharmaceutical Association are private, self-perpetuating corporations. The Pharmacopœia and the Formulary are published and sold by them. What profit, if any, is realized by the Pharmacopœial Convention and what salaries are paid are not known. The American Pharmaceutical Association makes an annual profit of approximately $8,000, but what salaries are paid are not known. The profit realized heretofore is independent, it is believed, of the sale of supplements, but future sales of supplements may be expected to increase whatever profit has been made; for if standards may be changed at any time through supplements it will be necessary for every practicing pharmacist who is engaged in interstate commerce within the meaning of S. 1944 to subscribe, and if the States follow the lead of the Federal Government in adopting such standards as official, every pharmacist will have to subscribe. Both of the corporations named are, it is believed, nonprofit corporations.

If Pharmacopœial and Formulary standards are to be adopted even in advance of their making as official standards, it would seem as if the Government might well define the scope of each book and determine how it is to be prepared and by whom. If authority to formulate legal standards is to be delegated to private corporations, it would seem as if those corporations might well be organized by special acts of Congress, and membership, procedure, prices of publications, and reports required. The rules applicable to the Pharmacopœia and the Formulary themselves should apply, of course, to any supplements that may be authorized. Notices of proposed changes should be given the public, opportunities to be heard, and effectiveness after publication should date from the expiration of some stated period after publication.

LEGISLATIVE AUTHORITY VESTED IN SECRETARY OF AGRICULTURE

This bill proposes to divest the Secretary of the Treasury and the Secretary of Commerce of the authority now vested in them under the Food and Drugs Act of 1906, to join with the Secretary of Agriculture in making rules and regulations to carry the act into effect. (See sec. 3, Food and Drugs Act of 1906, as amended.)

It proposes to vest all such legislative power in the Secretary of Agriculture. (See S. 1944, sec. 23 (a), and numerous other provisions of this bill.) The legislative authority that this bill proposes to vest in the Secretary of Agriculture is in fact far greater than that now vested in the joint board, in that it covers a

much wider range and to a large extent has the force and effect of law. It is far greater, it is believed, than has ever been granted to an administrative officer in time of peace.

Moreover, this proposed grant of power is accompanied by no safeguards to protect the right of the people. There is no requirement that the Secretary of Agriculture be competent to pass judgment on the many matters that the proposed rules and regulations promulgated by him may cover, and that means that such rules and regulations, while nominally those of the Secretary of Agriculture, will be in fact the rules and regulations of his subordinates. There is, however, no requirement that even the subordinates of the Secretary, by whom such rules and regulations must be prepared, will be sufficiently familiar with the matters of health and industrial interests involved to be qualified to perform that duty to the best interest of the public.

The manner of preparing and promulgating the proposed rules and regulations is utterly inadequate for the protection of the public interests. In some instances they can be prepared and promulgated without a public hearing. Even when a hearing is required, there is no statement of the nature and extent of the opportunities to be afforded interested parties and the public to be heard in person or by brief, nor is there any requirement that the hearings be public. The Secretary of Agriculture may summon a few subordinates in his Department, hear them in his office, and then promulgate such regulations as he desires, disregarding even the statements of his subordinates if he so desires.

Finally, there is no provision with respect to the manner in which the rules and regulations finally arrived at shall be promulgated so as to become effective. The signing of these rules and regulations by the Secretary is to be notice to all the world, and all parties interested in interstate and foreign commerce must examine daily the records of the Department of Agriculture to know what the law is on that day. And law enforcement officers, the bar, and the judiciary will have to find some method of knowing authoritatively and being able to prove the law on any particular day, in order that they may execute and enforce the law. And as if this were not enough, any rule or regulation promulgated by the Secretary may, under this bill, take effect instantly, even though industry and the trade can by no possibility comply with it for months thereafter, on account of changes in equipment and business methods required.

It is submitted that any proposal to vest in any administrative officer such legislative authority as is described above is unreasonable, impracticable, unjust, and inconsistent with our theories of government. The present system whereby such legislative authority as is granted is granted to a board consisting of the Secretary of Agriculture, the Secretary of the Treasury, and the Secretary of Commerce is far more reasonable; but even that system is defective in that it does not insure to the public and especially to interested parties the right to present their views before rules and regulations are promulgated, it does not insure publication in a way adequate to inform the public and interested parties concerning what has been done and to facilitate law administration, and it does not insure to interested parties adequate time for bringing their affairs into conformity with the new rules and regulations before they become effective.

The fact that many of the grants of legislative power by Congress to administrative officers, if not all of them, are open to the criticisms stated above does not justify the enactment of more legislation subject to the same criticism. It is urged, therefore, that in any legislation that may be enacted along the lines laid down in S. 1944, any grant of legislative authority be safeguarded as follows:

1. The grant of legislative authority shall be to a board—to such a board as now has authority or to some other board equally or better qualified—so as to make sure that such rules and regulations as are promulgated will represent the fair average opinion of a group of informed intelligent men and be influenced to a minimum by the personal equation.

2. No rule nor regulation shall be promulgated unless there has been previously published a notice of a public hearing, sufficient to apprise all interested parties of the fact that such a regulation is under consideration. The notice shall be published far enough in advance of the hearing to afford all interested parties opportunities to appear and be heard or to file briefs. All hearings shall be public insofar as is compatible with public interests.

3. No rule nor regulation shall take effect until after the expiration of some stated period after it has been approved by the promulgating authority and after the publication of that rule or regulation in some approved manner. Copies of such rules and regulations shall be available at all times to any person asking for them—a reasonable fee to cover the cost of publication to be payable if deemed desirable.

4. The regulatory authority shall report to the Congress in January of each year all regulations promulgated during the calendar year preceding. Such rules and regulations shall be published as an appendix or supplement to the Statutes at Large or in some other authoritative manner.

5. In event of an emergency, the President may waive the requirements for notice and publication for a stated period, and temporary regulations may be published to meet the emergency, but in any such event the regulations so promulgated shall be in force only so long as may be necessary to permit the promulgation of regulations in the regular manner.

In 1928, because of what seemed to be abuses of the regulatory authority then vested in certain officers of the Treasury Department, a bill along the lines stated above drafted on behalf of the American Medical Association and introduced in the House of Representatives by the then chairman of the Judiciary Committee. House bill 13412, Seventieth Congress, first session, A bill to regulate the promulgation of regulations in certain cases, with reference to alcohol and narcotics. A typewritten copy of that bill is attached.

Of course, the regulations to which the foregoing memorandum relates are only such as are intended to govern the conduct of the public and of industrial and trade interests; such as have the force and effect of law. Regulations intended to govern the conduct of officers and employees in the Department of Agriculture should obviously be promulgated by the Secretary of Agriculture, unhampered by outside influences and in such manner and form as the Secretary deems best.

The foregoing memorandum has reference to rules and regulations generally. Possibly standards and tolerances should be determined and established in the manner outlined above for the determination of the form and content of rules and regulations. On the other hand, in view of the highly technical character of the matters entering into the determination of standards and tolerances, it may be better to entrust their determination to some technically informed, permanent board. In any event it seems best that there should be such a board, if not to promulgate standards and tolerances, then to advise the promulgating authority with respect to them. A memorandum relating to the determination of standards and tolerances accompanies this memorandum.

[H.R. 13412, Seventieth Congress, first session]

A BILL To regulate the promulgation of regulations in certain cases, with reference to alcohol and narcotics

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That for the purposes of this act the following words have the meanings assigned to them, respectively, unless the context otherwise requires:

(1) "Department" means the Treasury Department and any bureau, division, office, and officer thereof.

(2) "Regulation" means any order, no matter how it may be officially designated, promulgated by the Department to regulate the importation, production, manufacture, sale, distribution, and use of alcohol and alcoholic liquors, or of narcotic and other habit-forming drugs, for nonconformity with which a penalty may be imposed, either by fine or imprisonment, or suspension or revocation of any registration or of any license or permit, or forfeiture of a right or privilege that has been granted by the Department. It does not include (a) orders merely interpretive of a statute, regulation, or decision, which do not change a rule of conduct or add to or substract from penalties already provided; or (b) regulations which affect only the internal management or discipline of a department; or (c) orders, judgments, and decrees made in the ordinary course of business in specific cases regularly before the Department for adjudication.

SEC. 2. No regulation promulgated by the Department by virtue of any act of, Congress now in force or hereafter enacted to govern the importation, production manufacture, sale, distribution, and use of alcohol and alcoholic liquors or of narcotic and other habit-forming drugs shall be of any force or effect unless—

(1) Notice of the contemplated promulgation of such regulation is given;

(2) A hearing is had wherein such persons as may be affected by such regulation may be heard; and

(3) The regulation is promulgated and published, all as hereinafter provided.

SEC. 3. Notice of the contemplated promulgation of a regulation shall be published in Treasury Decisions. This notice shall contain: (1) A copy of the proposed regulation; and (2) the date or dates, time or times, and place or places at which the Department will hear such persons as may be affected by the proposed

regulation. No hearing shall be held before the expiration of 15 days after the first publication of this order.

SEC. 4. Hearings shall be held by the Department in accordance with the published notice, at which any person who may be affected by the contemplated regulation may be heard in person or by counsel or agent and may file a brief. The Department shall have discretion to determine whether one or more hearings shall be held, whether such hearings shall be held concurrently or consecutively, and when and where such hearings shall be held, and shall designate the persons who are to hold them. The Department may at any such hearing continue the same, in its discretion, to any time and place that may then and there be fixed.

SEC. 5. Notice of any regulation that has been made by the Department shall be given by publication in Treasury Decisions. This notice shall include (1) a copy of the regulation as made or issued and (2) a statement of the time, not less than 15 days after the first publication of such notice, when the regulation will become effective.

SEC. 6. The Treasury, and every department thereof that promulgates any regulation within the purview of this act, shall submit to Congress annually on the first Monday in December a report containing all regulations so promulgated during the next preceding fiscal year. All regulations so reported shall be published as an appendix to the Statutes at Large of the United States. The first report submitted by the Department shall contain all regulations promulgated by the Department by virtue of any of the acts hereinbefore specified, in force at the close of the next preceding fiscal year. The subject matter of the report thereafter submitted to Congress shall be arranged in the same order as the subject matter of the first report.

SEC. 7. No provision of this act shall be construed as limiting the discretion of the Department as to the subject matter of regulations to be made or issued.

SEC. 8. The Department shall supply copies of all regulations promulgated by it on application, and, in the discretion of the Department, free or on payment of the reasonable cost thereof.

SEC. 9. The President of the United States may, in his discretion, declare that an emergency exists and suspend the provisions of this act during the continuance of such an emergency. Any regulation promulgated without notice and hearing during such suspension shall be published as speedily as may be practicable in Treasury Decisions. As soon after such publication as may be practicable notice shall be given of the day or days, time or times, and place or places at which the Department will hear such persons as may be affected by the published regulation, hearings shall be duly held, and the regulation as originally issued or as modified as the result of such hearings shall be repromulgated and republished, all in accordance with sections 3, 4, and 5 of this act. Any regulation promulgated without notice and hearing under authority of this section shall be in full force and effect, however, so long as may be necessary to allow for its repromulgation and republication in due course as herein provided.

SEC. 10. The courts of the United States shall take judicial notice of any regulation duly printed in the Statutes at Large under authority of this act, of any copy of Treasury Decisions duly authenticated under the seal of the Treasury Department, and of any copy of any regulation duly authenticated in like manner; and such publication or authentication, or both, of any such regulation shall be prima facie evidence of the making or issuing thereof in accordance with law.

SEC. 11. This act shall not impair the validity of any regulation promulgated prior to the passage of this act.

SEC. 12. This act may be referred to as the "Promulgation of Regulations Act."

SEC. 13. The expense incident to the carrying into effect of this act shall be borne by the appropriation for the expenses of the Treasury Department.

MEMORANDUM RELATIVE TO S. 1944

LABELING OF PRESCRIPTIONS

Section 8 (e) requires drugs not covered by other parts of the section, which relates to labeling, to be labeled so as to show the common name of the drug, if any, contained in it and the name, quantity, or proportion of each medicinal or physiologically active ingredient contained in it. Other parts of the same section require labeling in various other ways, as by showing the presence of habit-forming drugs. There is nothing to except prescriptions from the requirements of this section. Certainly it is undersirable to require the labeling of prescriptions in this manner and the bill should be amended accordingly.

COOPERATION WITH THE STATES

A provision requiring the Secretary of Agriculture to cooperate with the proper officers of the several States in enforcing the Federal and State food, drug, and cosmetic laws would do good. A provision of that kind is in the act under which the Bureau of Narcotics was organized and has, I believe, operated well.

Undoubtedly, Federal food, drug, and cosmetic officers often come into possession of evidence of offenses that might be prosecuted under State food, drug, cosmetic, or fraudulent laws. If they were compelled by law to disclose such evidence to State and local officers doubtless many cases could be brought to trial that now go unprosecuted.

ADVERTISING

Language along the following lines would seem fairly to cover false and misleading advertising:

"No person shall publish or distribute any advertisement that is false or misleading in any particular; but no person shall be convicted or punished under this provision when he shows to the court before which he is tried that when he published the advertisement complained of he did not know and could not by reasonable diligence find out that it was false or misleading; and no publisher or other officer or employee of a newspaper shall be convicted or punished when the advertisement published or distributed shows the name and address of the person in the United States criminally liable for any falsity or for any misleading information or design in it."

BRIEF OF LAURA A. CAUBLE, OF NEW YORK CITY, ON BEHALF OF HOME MAKERS FORUM, INC.

By appointment of Mrs. Otto Hahn, president of Home Makers Forum, Inc., New York, of which I am a director, the oldest club in New York which devotes its entire efforts to the interests and problems of the home, I present the resolution of unanimous approval and endorsement of S. 1944 in principle and urge its enactment in the interest of consumers.

This is the same resolution presented here at the December 8 hearings by Mrs. Malcolm P. MacCoy, president of the New York City Federation of Women's Clubs, Inc.

May I explain that this form of endorsement in principle is the form used by women's organizations to put themselves on record in case there may be delay or minor changes in a bill before its final passage; and to avoid approval of an emasculated bill apparently filled with teeth whose jaw is locked against enforcement.

S. 1944 may well have a few minor changes as suggested by Mr. Campbell; section 3 (c), page 4, line 21, change the period to a comma and add "and mascatory substances in chewing gum."

Section 17 (d), page 24, line 20, substitute "unless" for "if"; line 21, substitute "refuses to furnish" for "furnishes". Sec. 23 (c), page 31, line 2, substitute "In formulating regulations," for the word "The" at the beginning of the sentence.

Dr. Emerson cut the Gordian knot of "general agreement of medical opinion" by inserting "contemporary" after "agreement of"——

Mr. Donald G. Burke's suggestion of a conference for remedial action in the nature of an informal discussion and agreement on all problems between a manufacturer and the administration seems to be feasible though I naturally have not given careful thought to the relations.

Conference may be effective, quick, and inexpensive as a first step in understanding and getting at a subject.

Any question of proving intention, or "proof of intent" is impossible. The customer is cheated, endangered and/or injured, regardless of intention or intent.

Protect the consumer before the question develops to the danger point.

In relation to deteriorated drugs: It seems reasonable to establish limits of sale from producer to consumer on those products which may lose their quality or power of action by aging, for example ergot, so as to be useless when needed. Our

milk in New York bears a label "not to be sold after X date." Kodak films and other products are subjected to the same regulation. Why not?

"The bill robs the public of the right to self-medication."

It does not. It prevent advertisement or labeling of medicines for cancer, tuberculosis, diabetes, arthritis, and other diseases which are incurable.

It requires medicines which are not cures to be labeled, "Not a Cure—only a Palliative" when that is the truth.

"The bill will cause public and political resentment which will lead to reactions like those against the eighteenth amendment."

How can it when all the provisions of the bill are in the public interest, insuring that foods, drugs, and cosmetics will not jeopardize health and are honestly labeled and advertised?

"The bill gives too much power to the Secretary of Agriculture (to make standards; to place factories under a permit system; to enter factories for purposes of inspection; to enjoin a manufacturer from further violation of the law, etc.)."

There is no danger in conferring such authority, since it is a rule of the Supreme Court that any regulation or standard made as a result of congressional authority to do so, must not be unreasonable, capricious, or arbitrary, and besides all such conferred authority is subject to review of the courts.

"The bill authorizing the Secretary of Agriculture to place manufacturing plants under inspection, will build up an immense army of inspectors and make the Secretary a czar over industry."

This authority is pernicious and can be exercised only if the manufacturer applies for and requests inspection. Such service is now being carried on by some other agencies in a similar way and this is the way the inspection of meat is carried on. The meat packers benefit by it.

"The bill will increase taxes to care for an elaborate set-up for Federal enforcement."

The cost of enforcement of present law is less than 1 cent per capita. No new enforcement machinery is being set up. It will not appreciably increase cost—now 1 cent per capita.

"The bill will hurt business and depress values invested in advertising business."

If elimination of false and misleading advertisements will do so then such a consequence will result. But in the long run, advertising stands to be the gainer in the end.

"The bill will stifle the growth of food, drug, and cosmetic industries."

It will do so only to the extent of restricting unfair competition of small dishonest minority now using dirty, impure, poisonous, and injurious ingredients.

"The bill will destroy advertising efficiency."

The claim is absurd as it assumes that advertising which is now essentially honest cannot be both truthful and efficient. It will give a new psychological slant to advertising. It will inspire invention and create new needs for advertising. No honest advertiser needs to fear anything.

Because of my training in nutrition, public health, economics, and sociology at Columbia University and the following 20 years of active work upon public-health problems; because I have worked with every commissioner of health of New York since 1914 on some major health problem, and served as deputy commissioner of public markets of New York City in charge of information and conservation, and as teacher and lecturer on food, nutrition, and health in many localities I know conditions and may fairly qualify as an expert—one who knows the problems to be met and solved by S. 1944.

I speak for myself as a consumer with competent knowledge and information upon which to ground opinions and form judgments.

I have no business connections of any nature which influence my message to you, neither have I any reason to shirk my responsibility to other consumers or to hedge in my support of S. 1944.

I am for this bill. There may be slight minor changes some of which have been suggested. Make as few changes as may be consistent with the consumer's interest. Almost every speaker at the hearings of December 7–8 conceded that there is need for this bill. At the same time they offered suggestions which would destroy the bill. One of these was to insert the word "public" before the word "health" wherever it appears in the bill. That would destroy the bill. I have compared the act of 1906 as now in force with S. 1944 and with the sanitary code of New York City both of which measures I have observed in action since 1906. New York City has broad police powers and can quickly move to control new food or drug products, or any endemic, epidemic, or sporadic menace, or any threatening condition, fraud, or adulteration.

Note how quickly Commissioner Shirley W. Wynne, of the Department of Health, formulated definitions and enacted measures by the Board of Health to put under true labels in New York City the adulterated, fraudulent, and misbranded liquors which have flooded the Nation since the repeal of prohibition, December 1933. This was accomplished within a fortnight. Not many cities or communities have this police power.

It takes a long time to get a measure through Congress.

S. 1944 will give such control of these same frauds to the whole Nation. To meet this need alone this bill should be enacted with the opening of Congress, January 3, 1934. The consumer has the right to know. This knowledge and protection would be of immediate educational value, better than many programs of so-called "prohibition education for temperance".

No person with knowledge of the making of the act of 1906 and its amendments in force; or with the facts in relation to the wide gaps left in the original mouthful of teeth by the compromises which in order to get any law, had to be accepted at that time by Dr. Harvey W. Wiley and his supporters, the valiant body of scientists and officials and the determined and spirited members of the General Federation of Women's Clubs, who then had no votes and were merely the family buyers and enduring silent partners in the greatest business in the Nation—homemaking; or who has made observations or had contact with or experience with the enforcement of the act; no person who has made any definite comparative study of the act of 1906 as it now stands with this Copeland bill (S. 1944) can fail to understand that S. 1944 is a timely consumer's measure.

Also, that it is writen by and under the direction of men who with 27 years of experience with the behavior, enforcement, and court decisions established for the protection of business as well as the consumer and upon whose knowledge, information and opinion S. 1944 has been introduced by a Senator who also knows the difficulties of endorsement by experience as Health Commissioner of New York City and will be fair in his support of the measure.

Who could serve the consumers better or be fairer to the body of business which has reaped such rich harvests from the consumer?

The food and drug division commands the loyal service and trustworthy interest of tried men. The enforcement act is lodged in the really safe Department of Agriculture.

Some speaker proposed a commission or committee of scientists. How many of us can recall the "board" which was appointed in Dr. Wiley's day to "restrain" him. A great Governor of New York got rid of over a hundred boards and commissions in order to get a State government which could be made to function. We are still doing without those commissions in New York and I think one would be out of place in this food and drug work. Competent, scientific advisors are constantly available to the United States Government in and out of the Department of Food and Drugs. Their advice is freely given and sought.

S. 1944 will stop the holes left by the compromises and keep secure the teeth to meet the changes which the enlightening and complementary discoveries of biological, chemical, physical, and other scientific research have made possible and necessary, and will keep open the way for the early application of the principles to newer discoveries, products, and methods which may develop in the future.

Do I need to cite here the memorial to the Fifty-fifth Congress, second session, to show how changes and demands were met?

This memorial includes a recommendation for the passage of a food and drug bill which is almost identical with a bill drafted by Dr. Wiley and submitted to the various committees of Congress. This bill in Document No. 233, had the endorsement and whole hearted support of Dr. Wiley.

On page 3, section 5, the following definition is incorporated: "That the term 'drug' as used in this bill, shall include all medicines, recognized in the United States Pharmacopeia and National Formula and cosmetics for internal or external use." Cosmetics were omitted from the act as finally passed. This was a compromise.

Page 3, section 6, of the act, defining adulteration of food, sixth paragraph reads, "If it contains any added poisonous ingredient *or any ingredient which may render such article injurious to the health of the person consuming it.*" The italic words were omitted from the act as finally passed. That was another compromise. The substance of these words forms one of the important provisions recommended in the Copeland bill (S. 1944).

On page 4, section 6, paragraph 9, referring to mixtures or compounds sold under their own distinctive names it is "*Provided*, That the same shall be labeled,

branded, tagged, as prescribed by the Secretary of Agriculture so as to show them to be compounds and the exact character thereof."

Page 4, section 7 provides, "that the Secretary of Agriculture is hereby authorized to cause all compounds, mixed, or blended products to be properly branded and prescribes how this shall be done."

These are important provisions. They also were omitted from the act, as finally passed. The Copeland bill would provide this authority.

Members of the committee, when the act of 1906 was under discussion the same vociferous and determined lobby of proprietary medicine makers, drug dealers and bad food manufacturers or inert ones who were doing pretty well and did not want to be disturbed; many promoters and advertisers were on the ground as they now are, determined to prevent action at any cost—with this difference: There is a larger body of newspaper, magazine, outdoor, and radio advertisers presenting arguments, filling the mails, offering substitute bills. Their present mass methods of attack have gained horse sense. They follow a leader, turn a solid circle of heels to the next outer circle and an ever-widening circle the heels of which energize the minute men to a constant stinging attack.

Where does it strike? In the words of a Serbian girl refugee before the commanding general of the city in which she was called to account for herself. "I being now no more living, have no more fear, I speak the truth." I present exhibit A—marked for your use. If there was that much business in 1933, what became of the part of the $17,700,000,000 which ought to have been moving about? Who bought all these products? Would education and publicity, truth in advertising make such a difference?

Times have changed. Few producers of any foods are raising any objections to this bill. Some packers of food have asked for the factory inspection, e.g., the salmon canners. Scientific knowledge, education in home economics, biology, chemistry, the structure, function, growth, and nutrition of the human body, and the evolution of the food industry due to Dr. Wiley's leadership have changed the situation. The good law is eventually good for all of us.

Times have changed. There is constant emphasis on the fact that it is up to women to do their job well. They are better educated, better psychologists, better citizens than they used to be. They are thoroughly interested in this bill.

The consumer is not, and I think she cannot be, confused seriously by any statements about the dangers of this bill. Her confidence—indeed the confidence of the entire Nation—has been upset and shaken to the base. Ballyhoo does not move the woman citizen. She is quite resolute these days.

The cuckoo clock may call the hour and the half hour, but she is like the 8-year-old boy who turned the dial of the radio with the remark "The battle of the tooth pastes is on again, I use powder. Let's listen to something else."

"Voluntary inspection", section 22, has been called "a paradoxical complex, a dangerous experiment" at these hearings.

This inspection service is now offered by the Bureau of Agricultural Economics on perishable farm products. The authority to give it was introduced as the result of trade demand, grading of eggs, butter, fruit, potatoes, poultry, etc. The meat inspection law has been in full force for 27 years. Salmon packers have requested such service. Why should not packers of crab meat and other such foods have it? There have been trade demands for this section 22 though because it is so contentious, I think if it be not vital to the purpose of the bill, it might be modified. The question of the financing of this feature of the bill should not be questioned by any person who knows the results of the inspection of meat and milk alone.

When Pasteur discovered bacteria, the causes of food-borne diseases were soon known. When Dr. Harvey W. Wiley arose as the leader of the pure-food movement, food-borne disease was doomed. Today any city or community is ashamed to have cases of typhoid fever reported. "What is wrong with the milk? Or water?" In other disturbances "What food or drink have they had in common?" Isn't the cost worth while?

The combined effects of scientific research in foods and nutrition and the operation of the food and drug law and the education of the whole body of our citizens, through schools, the press and the health education in city and State and Nation, make it possible to choose and use the right food in the right combination at the right time anywhere.

The names carbohydrate, fat, protein, vitamin, endocrine gland, harmone meant little or nothing to women and home makers 25 years ago. Today one would seem to be a moron if she had not absorbed some of this newer knowledge. Some knowledge of these factors is part of the health education of every family.

The difference between the use and abuse of drugs in relation to health is beginning to be understood. We now have prescribed a diet instead of a tonic in convalescence. We rebuild.

This education is irresistible and will move on just as the education in foods has done. We need truthful labels and truthful presentation of values in every way, though advance can go on anyhow.

Now all the speakers against this bill have said the bill will take away the possibility of self-medication. It would make self-medication easier. It would give confidence upon which so much of the expected benefit is based. What is the present situation of the mother of the family who must bear and rear the children and keep up the efficiency of the family? Some health education has made her conscious of these questions:

1. The danger of neglect of the family health.
2. The knowledge of or faith in a few "simples" or remedies which have come down through the ages, which she uses to alleviate suffering, sooth the anxious patient, and quiet her own mind.
3. The vast blast and chorus proclaiming the new cures, remedies, and substances emphasized by radio, by the newspapers and magazines, though she learns these claims cannot be put upon the labels and gives little heed to the clamor.
4. The increasing number of proprietary products which bear the formula on the label.
5. The high cost of medical care and its frequent inaccessibility.
6. The probability and possibility of the county health unit and socialized medicine.

Is this the woman who has been here objecting to S. 1944? Certainly not. As she becomes acquainted with the bill she understands its helpful purpose and protection and favors it.

Who are the objectors to this bill? Are they shadows of 1906? Have they suffered no "sea change" in 27 years?

In 1887, when I was a very young girl, a friend was showing me her curio cabinet. Her mother whimsically remarked, "Show her the little pills." Into my hand was placed a small sample package of proprietary medicines which had been thrown in at the door as an advertisement and kept for some time as a curiosity. The box had 8 or 10 slender vials containing tiny white pills. Each vial was numbered and labeled "Specific" for some 1 of 8 or 10 major then known diseases and an alarming sequence of symptoms which made you wonder whether there was "no health in us", concluding finally at the bottom of the label in a heavier type: "Or fear of death." They don't do that now.

How many of us still carry horse chestnuts for rheumatism? Wear a Carnelian ring? Wear a sapphire? Or a rabbit's foot, etc. Or take Exity Ex Compound instead of a hooker of something else? The woman at home who voted for you as her Congressman or Senator can very well use as much intelligence in her choice of proprietary medicine as she did in voting for you in the election if you will give her a good chance to read labels which tell the truth, allow no false claims in the label or in advertising, and contain a warning in case of new and unknown or little known substances. (Note provisions in S. 1944, sec. 7 f (2) and sec. 8 e (1 and 2), quantitative formulas not required. Ingredient declaration required only where product is not a standard article.)

S. 1944 will help this woman very much.

I would like to present an exhibit of labels used by competent manufacturers who have confidence in their products and in the intelligence and observation of the consuming public. The formulas are given on these labels as will be required by S. 1944. On the shelves of the Mayflower Hotel drug store you will find many of these labeled articles. We would like to know why the United States must be reckoned as a backward Nation in respect to this labeling. None of our ordinary proprietary products can be shipped to any South American nation without a full formula on the label. Why not give home consumers the same protection?

The consumer would like to be relieved of another disadvantage. She is beginning to question the use of certain drugs and products. She cannot afford to buy these highly advertised substances and take them to a chemist for an analysis. Neither can she use such a scientist as Dr. A. Goettler and get his O.K. before she uses it. Dr. Goettler's analysis of the radium water used by Mr. E. M. Byers, of Pittsburgh, who died of radium poisoning, would have warned him to let it alone. The consumer has the right to protection. The Government can give it to her. Any manufacturer can make an analysis of any product on the market. So the objection to the revelation of the formula is

not valid. A manufacturer may not be able to tell by what combination or process a certain product was perfected. That is the clever protective secret of the good manufacturer.

Because of the individual differences of human beings as to the tolerances and allergies and some other differences, it is important to have such tolerances defined, standards set up, and note made of the behavior of such medicines under reasonable conditions. Several persons at the hearings recommended the insertion of the word "public" before "health" wherever used in the bill. I protest that suggestion. It would defeat the purpose of the bill.

Mr. Northam Warren, of the Associated Manufacturers of Toilet Articles, mentioned the annual turnover in the cosmetic industry in terms of many millions of dollars and said that only one one-hundredth of 1 percent of these cosmetics could be considered dangerous or fraudulent. I believe most of them could be eaten by a child with no worse result than a possible "tummy ache." But women and men have a right to know where danger lies.

The cosmeticians have missed the psychology of the consumers. They should be working for the passage of this bill. Why?

Women still believe they are taken at their face value. They try to live up to it and you will admit they do a pretty good job nowadays.

When education and industry took most of the interesting processes of making foods, clothing, interior decoration, and education out of the home and standardized them the women followed them out into business, and for the first time were paid for their work.

But in order to get the jobs they had to look young, fresh, and attractive—present good face value. The young Vassar graduate who had lived joyously all her life suddenly was faced with the complete collapse of her father's health after 4 anxious months of care, had to become provider. She got a job. A few days later, questioned by her boss as to her use of rouge and cosmetics, answered, "Yes, I do. I heard the office manager wouldn't hire a girl who hadn't good color. I had to have the job so I got my color for a quarter and now I can relieve my mother at night so she can sleep and I have money to buy food. I am doing my work all right?" She kept her job.

Now another woman who has often been ailing is Mr. Warren's best prospect. Get her interested in her face, complexion, skin, looking young. Yes, she leaves off all the doses, tonics, drugs, and doctors whom she never needed and spends a large part of $24,000,000 a year looking her best.

The honest manufacturer, the cosmetician, and the honest advertiser have nothing to fear. They will have an interesting time, more copy to write and a great increase in business under S. 1944.

Let us have the bill.

STATEMENT OF THE ASSOCIATION OF PACIFIC FISHERIES AND THE NORTHWEST SALMON CANNERS ASSOCIATION

I. The Association of Pacific Fisheries and the Northwest Salmon Canners Association, with offices at Seattle, Wash., comprise within their membership over 99 percent of the salmon packers of the United States operating in the United States and the Territory of Alaska. The industry as a whole does approximately $40,000,000 of business annually.

These associations submit to this committee that the present food and drug bill contains provisions which have been found to be adequate for the protection of the consumer of canned salmon. They believe that the drastic provisions of the proposed bill (S. 1944) are intended to meet difficulties found in the manufacturing, selling, and advertising of products other than food products.

Consequently, since the evils aimed at are nonexistent in the food industry, including the canned salmon industry, we see no need for the preparation of a very drastic bill which is inapplicable to, and is impracticable for, the salmon canning industry.

Therefore we petition that consideration be given to the feasibility of the preparation of a separate food bill. The problems of governmental regulation of food, drugs, and cosmetics must of necessity differ because of the difference in function and nature of the products involved in the three divisions. It cannot be truthfully said that evil in one division is of the same character and proportion as that in another, nor that it requires the same remedial and penalty devices for correction. Difficulties existent in the drug and cosmetic fields can be independently eradicated without the necessity of imposing unwarranted and costly impediments upon the manufacture and distribution of food products, including canned salmon, the cost of which ultimately must be borne by the consumer.

II. Specific objection is made to the following provisions, which, when incorporated into the suggested bill for food alone, if one is needed, should be materially modified, as follows:

1. Section 3 (a) (4): Substitute the word "has" for the words "may have." The salmon-canning industry believes that the determinations provided for in this section should be based upon fact rather than conjecture.

2. Section 11 and 7 (e), taken together, permit the Secretary to promulgate standards and provide that a food shall be misbranded if the label does not state such standards, including standards of quality, or if the product is not of the promulgated standard or standards.

The salmon-canning industry urges the amendment of these sections in regard to the preparation of canned salmon or canned foods, by the substitution of the provision suggested by the National Canners Association embodying the principle of the McNary-Mapes amendment to the Food and Drug Act. This amendment will allow the Secretary of Agriculture to set a standard for each class of canned food calculated to promote honesty and fair dealing with the consumer. That is the industry's conception of proper and practicable governmental regulation, namely, to enforce a minimum standard of quality below which a manufactured product may not fall. Anything further is regimentation that extends beyond principles of our existing system of government.

The industry opposes the principle that government officials should dictate the forms and types in which a product is to be marketed. Those forms and types must be flexible. They result from a variety of factors unsusceptible of fixed standardization. They adjust themselves naturally by consumer preference in a competitive field. By unwritten economic laws they bear a close relation to costs.

Furthermore, the industry feels strongly that any such standards cannot be set up so as to be capable of efficient enforcement and that any efforts at enforcement necessitate procedural difficulties that make the scheme impractical.

For example, in the salmon-canning industry there are five varieties of salmon which may be canned—Chinook, Red, Coho, Pink, and Chum. The promulgation of standards within these five varieties is impractical and impossible. Conceivably, there is no objection to a requirement that the particular variety of salmon be designated.

3. Section 12 as drafted would permit the Secretary under conditions determinable within his own discretion to license all food factories by means of a permit system which may be suspended arbitrarily by him. The nature of the operations involved in packing salmon in Alaska render such a provision for administrative power particularly objectionable to the salmon-packing industry. Due to the short season and the isolated character of the area in which operations take place the revocation of a permit under section 12 (b) on the ground that certain regulations were being violated in the packing operations then under way would be equivalent to an administrative determination that for a particular season no packing could be allowed. Any right of appeal for judicial determination would be an insufficient remedy, since it would serve only to lock the stable after the horse was gone. The provision that the permit may be reinstated after hearing, inspection, and a finding that adequate measures of correction have been taken, is an illusory safeguard for the same reason.

The industry feels that the legislation of these drastic powers into an administrative official is a threat to its very existence because the peculiar conditions surrounding the industry nullify the effectiveness of its constitutional rights of judicial appeal.

Section 16 (e) provides further that foods manufactured by a person not holding a permit under section 12 shall be destroyed. The industry feels that this provision is unnecessarily drastic. The words require the administrative officials to destroy the whole shipment without permit. This requirement provokes an uneconomic and unnecessary waste and a taking of property without due process of law. Furthermore, some provision should be made for the return to the manufacturer of goods processed during the period in which the permit was canceled in event the permit is reinstated and the goods are given a clear bill.

The association also indorses the proposal made by the National Canners' Association for the amendment of section 17 (b) regarding penalties and confirms the reasons advanced by that organization as being highly important in the salmon-packing industry. The association recommends the amendment of section 18 to provide for the proof of knowledge on the part of the person charged sufficient to amount to a criminal intent. It is somewhat difficult to impose criminal liability upon a corporate official located in the United States

for some minor act done by a subordinate in Alaska where he has no knowledge of such act and had he such knowledge would clearly have forbidden it.

The association concurs in the necessity for and desirability of the amendment to section 21 regarding publicity suggested by the National Canners' Association. The elimination of the phrase "for the protection of the consumer against fraud" will remove the authority to issue precautionary information in advance of findings of fact. This seems only fair to the food industry, since the provision is obviously aimed at drugs and cosmetics. A separate provision relating to them might be inserted. This association recommends the complete deletion of section 24 as conferring upon the consumers no greater rights than they now have. It is the type of provision which will be conducive to unwarranted and fictitious suits instituted solely for the purpose of compelling the defendant to settle.

The American food manufacturers, including the salmon packers, are as much interested as the Government in preventing the sale of adulterated, poisonous, or unhealthful foods. It should be recalled that they are as much concerned about consumer interests and health as are any other agencies. Nevertheless, it must likewise be remembered that the food industry represents investments of many millions of dollars, that in the salmon-packing industry, because of conditions depending entirely upon nature or upon conservation activities of the Federal Government, in many seasons this investment yields no return whatever. To permit complete administrative control of this industry, to permit arbitrary or mistaken seizures of thousands of dollars worth of food, to permit, as this bill contemplates, the complete cessation of activities, is a matter of great moment to those in the industry.

We believe that in any act proposed, adequate provision for complete court review should be provided. This is intended as no reflection upon any administrative official. But a law as sweeping as this can be arbitrarily enforced. We feel that the interest of the public will not be in any way affected, and the necessities of the situation require that adequate court safeguards be thrown around administrative action under the bill. In most instances resort to the courts is not necessary. In the majority of cases the industry will cooperate in the formulation of any regulations or in any action under them, but the association insists that the amendment proposed by the National Canners providing adequate court review of action under this act be incorporated in it.

In conclusion, we wish to say again that it is not only unjust, but possibly improper legislative action to associate in one comprehensive statute a variety of products—drugs, cosmetics, and foods—which involve wholly different techniques of manufacture and sale and the problems in each of which are wholly different. We have no opinion as to the necessity of some of the provisions of the act as applied to other fields, but we believe it is clear from the history of the cooperation between the food industry and the Government that most, if not all, of them are completely unnecessary in the case of canned foods, particularly canned salmon.

SAN FRANCISCO CHAMBER OF COMMERCE,
Washington, D. C., December 5, 1933.

Hon. HUBERT D. STEPHENS,
Chairman Commerce Committee, Washington, D.C.

MY DEAR MR. STEPHENS: I beg to hand you, herewith, brief from the San Francisco Cocoa Trade Committee, on the subject of mold tolerance on cocoa which will be considered at a meeting of your committee December 7, when the Tugwell pure food and drug bill is to be taken up.

San Francisco's importations of cocoa beans have dropped 50 percent since October 1, when the 5 percent mold tolerance went into effect, while there has been no decline at New York. The new 5 percent tolerance stands out in bold relief when compared with the international standard, fixed by long experience of 12 percent.

If present conditions continue it seems inevitable that San Francisco's cocoa bean import trade will be slowly strangled.

I trust you will give this matter your usual careful consideration.

Sincerely yours,

C. B. DODDS,
Washington Representative.

MOLD TOLERANCE ON COCOA

The international standard for mold tolerance of 12 percent, fixed by long experience, meets average crop conditions and does not diminish the quality of any finished cocoa product. No necessity has been shown to arbitrarily reduce this standard to 5 percent, practically amounting to an embargo on all Pacific coast importations of consumption cocoa beans. The average yearly mold percentage of Accra cocoa beans, representing more than 60 percent of the world's crop, is 4.1 percent as stated in "Foodstuff's Round the World", United States Department of Commerce, dated August 19, 1932. The Brazilian statistics are about the same. Cocoa beans are semifermented and therefore subject to deterioration in transit and the longer water borne trip to Pacific coast ports puts us at a definite disadvantage with the East Coast, as proven by actual experiences. The Food and Drug Administration does not admit such deterioration, although it has made no tests whatever on Pacific coast imports. Its theory is pure assumption.

According to the Department of Agriculture's ruling of August 26, 1931, all cocoa bean shipments arriving after October 1, 1931, could not be segregated any more, when a partial excess mold count was found, except if destruction of the nonpassable portion was agreed to. This abrogates the provisions of the tariff act, granting importers the right to either reexport or destroy. Acting Secretary of Agriculture, R. W. Dunlop, justifies this action in a letter dated October 16, 1931, as follows:

"Under the provisions of the Federal Food and Drugs Act, section 11, the broadest discretion is conferred upon this Department in the control of importations of food and drugs. It may make a conclusive finding of fact as to the admissibility of such articles into the country. It follows, therefore, that having absolute authority to determine whether, under the law, articles of food or drugs should be prohibited entry, it may make a qualified finding which will permit the entry, conditionally, of partly adulterated or improperly branded consignments, which can be made to conform to law. The Department in such instances possesses authority to prescribe the condition upon which such consignments may be entered, and may impose such restrictions upon the importers thereof as it may deem necessary or apparent, therefore, that the Department may, within the limits of its lawful authority, make its findings and recommendations as to the admissibility of consignments such as those in question, dependent upon the destruction of the unfit portions thereof."

Large East coast importers can make arrangements with steamship lines, to ship rejected cocoa beans, at a nominal cost, to Toronto or Liverpool or continental ports where such shipments can be sold a few days later at full value if below 12 percent mold. Pacific coast importers are at such a disadvantage that business is practically impossible without covering the risk by adding to the cost, thus making us noncompetitive. It is doubtful if Congress ever intended to give such powers to the Food and Drug Administration.

The effect of the nonsegregation ruling is shown in the precipitious decline of imports and its resultant damage to the industry. Any actual comparison between the amount of rejections on the East coast and on the West coast is purely academic and simply means that western importers understood the consequences of this ruling. Mr. P. B. Dunbar, Assistant Chief of the Food and Drug Administration, in a letter dated June 20, 1933, arrived at a fallacious conclusion when he stated:

"The administration had occasion to make a study of its activities on cocoa bean entries from June 1932 until recent times. This study revealed that during the period there were refused entry at the port of San Francisco a total of 364 bags as against detention of 74,000 bags which were offered for entry at the port of New York.

"Comparison of these figures does not make it apparent that the industry on the west coast suffered more severely than that on the east coast."

The abrogation of segregation and the right of re-export is an intolerable academic interference in the delicate machinery of foreign trade. It is an usurpation of power on the part of the Food and Drug Administration, questionable as to its legality and destructive as to its consequences.

SAN FRANCISCO COCOA TRADE COMMITTEE,
H. VANDEL.

HOUSE OF REPRESENTATIVES,
Washington, D.C., December 23, 1933.

Hon. ROYAL S. COPELAND,
Chairman Senate Committee on Commerce,
United States Senate, Washington, D.C.

MY DEAR SENATOR: In connection with Senate bill 1944, proposing amendments to the Food and Drugs Act, I beg to hand you herewith, at their request, statement of the California Fruit Exchange of Sacramento, Calif., with the request that it be inserted in the printed hearings.

This organization is a growers cooperative marketing organization with a membership of several thousand and its management is of an exceptionally high character.

Will you kindly advise me whether additional copies of this statement are desired for the use of the committee. If so, I shall be glad to have the Exchange furnish them.

Sincerely yours,

FRANK H. BUCK.

STATEMENT OF CALIFORNIA FRUIT EXCHANGE, SACRAMENTO, CALIF., RE S. 1944—PROPOSED NEW FOOD AND DRUGS ACT

(The California Fruit Exchange, with headquarters in Sacramento, Calif., is a nonprofit, growers' cooperative marketing organization. It handles in a normal year approximately 15,000 carloads of fresh deciduous tree fruits and grapes. Its membership totals about 5,000 growers.)

In presenting this statement, the California Fruit Exchange wishes to go on record at the very outset to the effect that it endorses, without reservations, the principles involved in pure-food legislation. The rights of the great body of American consumers are paramount in food merchandising. They are entitled to every protection from a health standpoint, and no organization which fails to recognize this simple fact can be successful for any long period of time.

The proposed bill, however, goes far beyond these basic principles. As a whole, it is dangerous in character. Without analysis it has a very deceptive popular appeal, but basically the bill is predicated upon a complete shift from commonly accepted legal concepts to bureaucracy. The act is a criminal statute, conferring directly upon the Secretary of Agriculture authority to make rules, regulations, standards and tolerances which will have the full force and effect of law, and from which there is no appeal except to the courts. No method is provided for the right of appeal within the department; no separation is made between willful violations and technical violations in the matter of fines; and in our judgment it goes far beyond anything required to protect the public health.

Originally, and up to this time, the Food and Drug Administration has been a regulatory, police body. Its primary duty has been to protect public health through the existing Food and Drugs Act. This bill, however, gives the Secretary and the Food and Drug Administration, who will enforce the act, the right to impose mandatory grading standards on food industries, including perishable fruits and vegetables. Such grading standards as have been recommended by the Department of Agriculture to date have emanated from the Bureau of Agricultural Economics, an organization which is both service and regulatory in character, but which has been composed in large measure of men who have had actual practical experience in the handling and marketing of agricultural commodities. These men have not been essentially police officers, and they have the right attitude toward the practical phases of the agricultural industry. The various grading standards recommended by this Bureau to date also have been for the most part, permissive in character. In some cases they have been mandatory, but only with the consent of the industry involved.

We feel, therefore, that foods should be separated from the proposed measure; that the present Food and Drugs Act should be revised as a pure food bill; and that with the support of the many court decisions which have been obtained over a long period of years since the present measure has been in force and effect, it should be strengthened in some details rather than attempting to include foods with drugs and cosmetics in new legislation.

Obviously, no one can defend the indiscriminate, reckless sale of dangerous patent medicines which are incorrectly or incompletely labeled and falsely advertised. The food industry as such, however, is certainly not in the class with these fake remedies. On the whole, it is an industry in which the best of practices prevail, and in any event is large enough to stand independently and on its own feet.

Should it prove impossible at this time to divorce foods from drugs and cosmetics, and give us a separate act, attention is directed to the following in S. 1944:

Section 2, paragraph (e), line 20, on page 2 of the printed bill defines the term "interstate commerce" as meaning "commerce between any State or Territory and any place outside thereof, or between points within the same State or Territory, but through any place outside thereof." This immediately extends the jurisdiction of the Secretary of Agriculture to export shipments; a new idea in defining interstate commerce. Why the Secretary of Agriculture should assume jurisdiction over shipments of any food commodity to foreign countries is impossible to determine. Surely our departments of the Federal Government have enough to do to protect our own people and the citizens of this Nation without attempting to foist on foreign countries their opinions and ideas. The peoples of central Europe for example, may, because of food habits or financial reasons, choose to buy certain substandard goods. If they care to do so, that is their business. The restrictions and laws of foreign countries are varied and wide enough at present to protect their own nationals. There is no need for the United States entering this field.

Section 3, the word "shall" in line 22 should be eliminated and the word "may" substituted in lieu thereof, so that the first sentence reads, "A food *may* be deemed to be adulterated" instead of "*shall* be deemed to be adulterated." The ambiguous language in paragraph (a) of section 3, "if it *is* or *may* be dangerous to public health" should read "if it *is* dangerous to public health."

The milk people are somewhat afraid of lines 12, 13 and 14 on page 4 in section 3, reading among other things "if any valuable constituent has been in whole or in part extracted therefrom." What about skim milk? Certainly valuable constituents have been removed from the subsequent product, but the final product is in no way dangerous to public health. The department may explain that they would not proceed against such products, but the language gives them authority to do so.

In section 6, "Misbranding", paragraph (a) is replete with inferences and presumptions. It states "if its labeling is in any particular false, or by ambiguity or inference creates a misleading impression regarding any food * * *." The words "or by ambiguity or inference creates a misleading impression" should be eliminated. To vest in the Secretary or the Food and Drug Administration the right to interpret what is ambiguous or inferential or what creates misleading impressions, is certainly dangerous; the language is anything but specific; and any Federal criminal statute should be specific if it is going to be fair.

In paragraph (b) of section 6, subparagraph (2), it is required that an accurate statement of the quantity of the contents and terms of weight or numerical count may be prescribed by regulations of the Secretary. Reasonable variations are permitted as to small packages of foods. Certainly reasonable variations should likewise be permitted for packages containing fruits and vegetables which as you know from experience, vary in weight, and tolerances or variations must be permitted to accommodate this necessary situation.

Paragraph (c) of section 6 requires the placing of the label in a prominent and easily seen position, readily intelligible to purchasers. What about bulk retail sales of fruits and vegetables? If this authority is extended to such sales, enforcement would be difficult, if not impossible. Bulk sales should be exempted from this requirement.

Section 7, "Misbranding of Foods", is an omnibus section. Fruits and vegetables should really be exempted entirely. The word "shall" in the first sentence should be stricken out and the word "may" substituted in lieu thereof. Paragraph (a) authorizes the Secretary to prescribe the standard of fill in packages, which introduces at once the matter of quality, grades, and standards, thus going far beyond the necessities of a public health measure. There is no similar provision in the present statute. If language is used such as "if its container is so made, formed, or filled as to mislead the purchaser" permission should be given to use caps, cushions, pads, packing material of all kinds normally utilized in shipping fresh fruits and vegetables.

Subsection (f) of section 7 on page 9 requires on the label the common or usual name of each ingredient in the package, in order of predominance by weight. Food industries, other than the fresh-fruit industry on the Pacific coast, object strenuously to this provision. In many cases it is impossible to comply with such a requirement. It carried to its conclusion, it would necessitate revealing secret and patented formulae to competitors. The contention that the patent laws fully protect the food manufacturer in this regard is untenable, because

clever imitations might be developed through the revelation of secret processes, and certainly it would encourage close similarity to any product which had proved a success from a merchandising standpoint

Section 9, entitled "False Advertisement", is exceedingly far-reaching and dangerous. It is of course all right to say that advertising shall not be untrue, but to say as this section does in paragraph (a) that an advertisement shall be deemed to be false if it "by ambiguity or inference creates a misleading impression" is again presumptive language. This entire clause should be stricken out. It is altogether too indefinite.

Section 10, fixing tolerances for poisonous ingredients in food, and vesting in the Secretary complete authority to establish these tolerances, in our judgment goes altogether too far, and is an assumption of unwarranted arbitrary power. The right of appeal should be given in this section to a competent advisory council, the complexion of which should be set forth in the act with proper safeguards, insuring the selection of a fair court of appeal within the Department itself.

Section 11, entitled "Definitions and Standards for Food", introduces a new thought in food and drug legislation. It vests in a regulatory, police body the authority to fix and establish not only definitions of identity, but standards of quality and fill of container for any food. Fruits and vegetables should be exempted from this provision. As already pointed out in the general introduction of this statement, permissive grading standards for fresh fruits and vegetables are now promulgated from time to time, and upon consultation with interested industries by the Bureau of Agricultural Economics. The same organization has been conducting the nation-wide shipping point and terminal market inspection service where these grades are put into practical operation. This organization has been doing that work for many years. There is no reason why it should be transferred to the Food and Drug Administration, and likewise no reason why, particularly for fresh fruits and vegetables, such grades should be made mandatory in character. This goes far beyond the necessities of protecting public health.

Sections 12 and 13, "Permit Factories and Factory Inspection", are not in the present law. If enacted, it means more officials, more inspection, and all to no purpose. There is ample authority for condemning food products at the present time which are in violation of good practice, or dangerous to public health. Fresh fruits and vegetables should be exempted from such regulations. The dried and canned fruit industries of this State are very much opposed to these two sections also. They point out that even permissive factory inspection would eventually force all food manufacturers to submit themselves to this activity. If small manufacturers availed themselves of permits and factory inspection, and advertised the fact that they were under Federal supervision, it can easily be seen that as a matter of self-protection, all would have to enter the field.

Section 14 authorizing carriers engaged in interstate commerce to permit officers or employees of the Department to copy all records showing the movement in interstate commerce of any food, the nature, kind, quantity, shipper, and consignee thereof, is another example of too much Government interference. Federal authorities have plenty of law at the present time enabling them to secure records where needed. They can subpena witnesses, books, papers, and records of all kinds from the shipper or manufacturer, There is no need for this additional authority.

Section 16 on seizure is exceedingly drastic. It does not provide, even in cases where there is reasonable doubt, for the release of the goods under bond. It places the articles immediately within the jurisdiction of the court. It really permits destruction of a perishable product without legal recourse. This language should be analyzed carefully and proper safeguards introduced

Section 17 on penalties, makes no differentiation between willful violations and wholly innocent violations. It should provide for remedial action through conference with the Secretary, and perhaps the advisory council above suggested, but penalties should only be imposed in the event of willful violation. It will be noted by comparing with the present Food and Drugs Act, that the fines have been substantially increased. Publishers and advertising agencies are solicited for support in this section, by exempting them from prosecution in paragraph (d), when they furnish the Secretary with the name and post-office address of the person who caused them to disseminate advertisements deemed to be false or misleading. Often times the advertising agency may be equally guilty with the advertiser.

The voluntary inspection service provided in section 22 should provide that if it is taken advantage of by any industry, such as the fresh pear and apple industry, for example, that the findings of the inspector at point of origin are absolutely final. The Food and Drug Administration has consistently evaded assuming this responsibility, although they are perfectly willing to seize goods after they have moved in interstate commerce and condemn them. We believe that if voluntary inspection service is instituted, at point of origin, that the findings with reference to spray residue tolerances should be final, conclusive and binding.

In section 23 the Secretary's findings are made conclusive. They should be made prima facie evidence in court but not conclusive.

Section 24, Liability for Personal Injury, is very dangerous. It should be eliminated, as it merely places the stamp of approval of the Federal Government on "ambulance chasers" and persons attempting to take unfair advantage. One large food industry organization maintains a large fund for the express purpose of fighting professional damage seekers. There is plenty of law on the statute books at the present time under which a person can sue for damages. This additional language is not needed.

It is reported on good authority that many of these provisions, if enacted into law, will be introduced into codes and marketing agreements, which again indicates the need for closest attention to this bill.

While this analysis deals with the measure from the standpoint of the fresh fruit industry, we subscribe whole-heartedly to the complete analysis made by the State Chamber of Commerce, in which we had a part, and herewith attached. This is the latest revised copy, and analyzes the measure from the standpoint of our many industries here in California.

Respectfully submitted.

F. W. READ,
Manager Standardization Department.

THE NATIONAL DAIRY UNION,
Washington, D.C., December 20, 1933.

Hon. ROYAL S. COPELAND,
Senate Office Building, Washington, D.C.

MY DEAR SENATOR: Representatives of the butter industry have been giving very careful attention to the proposed amendments to the Food and Drugs Act and wish to suggest certain charges which we believe your familiarity with the butter industry will lead you to support.

We are enclosing herewith a brief to be included in the record of the hearings and wish to ask you to give it your personal attention.

You will note that the three amendments which we suggest and the reference to the language of three other sections are in no way critical of the general proposals incorporated in your amendments but call attention only to matters which are we believe limited almost exclusively to the butter industry. This is explained in the brief. Specifically we ask—

1. That the Butter Standards Act should not be repealed.
2. That the definition of a "second offense" shall be such as to eliminate absolutely unintentional offenses and offenses which may be committed without intent in entirely different plants or under entirely different circumstances than those accompanying a first offense.
3. That after seizure notice shall be next the actual owner and he be given samples.

These are our major interests.

Yours sincerely,

A. M. LOOMIS, *Secretary.*

BRIEF ON PROPOSED AMENDMENT TO FOOD AND DRUGS ACT KNOWN AS "S. 1944" OR "H. R. 6110"

In the commercial manufacture of butter it is not possible to control the exact composition of all parts of any individual churning.

Butter is not made by weighing and putting together certain ingredients and stirring them up like a woman making a cake.

The process of butter making is one of eliminating moisture so as to leave the finished product with a legal content of butterfat.

Churns used in the butter-manufacturing plants are cylinders or drums often 6 to 9 feet in length and from 4 to 6 feet in diameter, making as high as 1,200

pounds of butter in one churning. It is physically impossible to control the physical conditions or the exact composition of the resulting butter in all parts of the churns at one time, and the butter in different parts of the churn may vary as much as 1 percent of butterfat.

The judgment of the buttermaker comes into play in dealing with the variations in temperature and in the variations of butterfat consistency which, due to different feeds, different times of year, and other condition may be hard or soft in texture and therefore carry more or less moisture. Proper manipulation by the buttermaker is subject to variations of human judgment and therefore subject to human errors.

In sincere efforts to comply with the present law providing no tolerances many manufacturers have frequently made exact tests, taking samples from various parts of the same churning. These samples have shown a variation in butterfat content as high as 1 percent. In general practice variations up to one half of 1 percent are common. It is entirely impractical in commercial operation to make numerous tests from each churning.

The large number and comparatively small size of the majority of the butter-manufacturing plants make it impossible to have highly skilled, technically trained buttermakers in charge.

Consideration should be given to the fact that there are more than 5,000 creameries operating in the United States. These plants are in charge of buttermakers as a rule well trained, but not equally efficient in making laboratory tests.

The best buttermakers have from 2 to 3 years' training, including the necessary technical knowledge obtained in an agricultural college course. Men of this training can be employed in the larger plants. To provide men for the smaller plants the agricultural colleges maintain a shorter course, and the smaller plants are in charge of such men as are available. At times the testing apparatus may be slightly out of order and exacting duties such as attention to a steam boiler may not at all times permit the meticulous care required to maintian a standard. Under all of the considerations which we are stating we are pointing out that the determinations may vary unintentionally and even adequately equipped and trained laboratory experts are frequently confronted with the same variations.

We are as much concerned as the officials of the Food Administration are, that errors due to negligence or to the deliberate employment of improperly trained personnel should not be permitted but the unintentional error or the slight deviation from standard due to uncontrollable causes should be allowed for.

Section 26 in the proposed measure repeals the Butter Standards Act of March 4, 1923. At the annual meeting of the American Association Creamery Butter Manufacturers, December 5, 1933, the following resolution was unanimously adopted:

Whereas Senate bill 1944, cited as the "Federal Food and Drugs Act", proposes to repeal the present standards for butter and which standard was executed by the Congress of the United States, and

Whereas that standard was promulgated after extended and full hearings and the entire butter industry of this country is now adjusted to it, and since it fully controls the industry and protects the consuming public; be it

Resolved, That the American Association Creamery Butter Manufacturers, in annual meeting, is opposed to the repeal of the Butter Standards Act of March 4, 1923.

We have interviewed the Secretary of Agriculture and others and cannot find anyone in favor of this repeal; therefore, it is perhaps an oversight, nevertheless, section 26 (a) of S. 1944 provides that the Federal Food and Drugs Act, as amended, namely U.S.C., title 21, sections 1 to 15, shall be repealed. Section 6 of said U.S.C., title 21, is the act to define butter and provide a standard therefor. Passed March 1923, chapter 268, 42 Statutes 1500, so that under the proposed bill, that section of the law is repealed, it being, as indicated above, section 6 of the sections 1 to 15 of the U.S.C., title 21.

We suggest that section 26 in the proposed measure be amended at the end of line 20 to read:

"That section 6 of said U.S.C., title 21, an act to define butter and provide a standard therefor, approved March 4, 1923, shall remain in full force and effort also provided."

SECTION 17 IN PROPOSED MEASURE

We respectfully submit that the general principle of increased penalties for second or subsequent offenses should only be directed at repetition of improper practices by the individuals in management or those in physical control of the production operation.

If substandard products are repeatedly found coming from the same plant, caused by conditions well within the control of the management, such repeated violations of the act are prima facie evidence of intent to violate the law, and we offer no objection to increased penalties in such cases.

With regard to multiple-owned plants under separate and distinct management, we submit that second or even moderately repeated substandard shipments, are not pirma facie evidence of deliberate intent to violate the law unless such repeated substandard products come from one single unit or plant.

In the butter-manufacturing industry the ownership and operation of multiple plants is common and is increasing, both among the privately owned units of the industry and the cooperatively owned units of the industry. A striking example is found in one large cooperatively owned unit which now has exclusive sales rights under specific brand name for the butter produced in more than 350 plants. Multiple ownerships in tne industry ranges from 2 plants to 350. The danger of increasingly heavy penalties for second and subsequent offenses charged to the same company or the same responsible sales agency and its inequity is self-evident when the control of the composition of the product rests in the individual buttermaker in one plant for one violation and in a buttermaker in another plant in a different locality for the next violation.

We therefore recommend that section 17 (6) (b) be amended to include the following:

"*Provided*, That the penalty for such subsequent offense shall be conditioned that the offense was committed in the same processing plant or factory as the first offense or with the knowledge of the general management."

SECTION 16 IN PROPOSED MEASURE

The owners of seized articles, especially a perishable product like butter, should have prompt notice and if they desire a representative sample of the article seized, so that they might in an intelligent manner and in the good cause of justice, prepare a defense. We recommend the following amendment to section 16:

"In case of seizure, notice shall be given at once to the actual owner and they shall be allowed a representative sample of the article seized."

SECTION 18 IN PROPOSED MEASURE

The language in this section should be made clear so that personal liability will not attach against anyone unless knowingly taking part in a violation.

SECTION 21 IN PROPOSED MEASURE

Publicity is a powerful weapon. It would seem that the manufacturer should be given some protection under this section. The proposed measure is a strenuous one and the penalties are heavy. We speak only for those who are drawn into court by reason of accidental and unintentional violation.

SECTION 22 IN PROPOSED MEASURE

We object to this section for the reason that it is entirely discriminatory. The larger establishments can afford to pay for this inspection service and the advertising value. This service cannot be given to the small operator and his plants are by far in numerical majority. He is not in position to pay the Government for this service.

There are many creameries throughout the United States, and many of them are moderate in size, and expensive help or experts cannot be afforded or employed. In that respect creameries differ from most other plants where food is prepared, processed or manufactured.

The making of butter is an old industry, a sort of natural evolution. Fraud is seldom met with. Creameries are found not alone in large centers but in the smaller villages; and, as stated, the labor employed usually receives modest wages.

Thus, human failings should be somewhat allowed for; and if a churning of butter goes out slightly below the legal standard, such an act might be accidental and entirely unintentional. The judge of the curt should be permitted to recognize this when the penalty is meted out.

AMERICAN ASSOCIATION CREAMERY BUTTER MANUFACTURERS,
By W. JENSEN, *Secretary-Manager*.
THE NATIONAL DAIRY UNION,
By A. M. LOOMIS, *Secretary*.

LETTER OF MERRILL HUTCHINSON, PRESIDENT HUTCHINSON ADVERTISING CO. MINNEAPOLIS, MINN., TO SENATOR HENRIK SHIPSTEAD

MINNEAPOLIS, MINN., *December 15, 1933.*

The Hon. HENRIK SHIPSTEAD,
Minneapolis, Minn.

MY DEAR SENATOR: On behalf of the group here present, I want first to thank you for your courtesy in granting us this opportunity to meet with you and present certain information respecting the provisions and possible consequences of the proposed Federal enactment S. 1944 and H.R. 6110, commonly designated as the Tugwell bill, which we understand will come before Congress in January.

We, of course, have a direct and vital interest in this bill. We do not challenge the sincerity of United States Senator Royal S. Copeland or Congressman William I. Sirovich, who appear as sponsors of the bill, although admittedly not its writers. We raise no question as to the possible need for amendment of the present Pure Food and Drug Act. We were prompted to request your consideration today because of our confident belief that you desired to be in possession of all available information respecting the likely results of the application of any new legislation, and particularly as it might affect not only the entire body of your constituents but also the business interests with which such constituents' livelihood is inseparably woven.

With your full comprehension of the vicissitudes by which business in general has been beset during the past few years, and the delicate balance between profit and loss figures which obtains in most businesses today, we realize that we do not need to tell you that immediate consideration of any measure of the import of the Copeland bill, not having the urgency of some of the so-called emergency legislation hastily enacted at the last term, merely serves to aggravate further—and we believe unwarrantedly—an already delicate situation. Many representative business men are in agreement that if there is any single obstacle contributing more than others to retardation of economic rehabilitation, it is the factor of uncertainty: uncertainty respecting the imminence of enactment of inimical legislation, Federal and State; uncertainty respecting interpretations and applications of existing experimental legislation, such as that affecting the monetary situation; uncertainty concerning conditions of peace, war debts, tariffs, armament, and many others in the foreign countries.

In its present form, Senate bill 1944 is loosely drawn, indefinite, impractical, unduly severe in penalties prescribed, and contravenes established court procedure. As drawn, the bill does not represent in substance what its title purports to have it constitute; namely, a bill "to prevent the manufacture, shipment, and sale of adulterated or misbranded foods, drugs, and cosmetics, and to regulate traffic therein; to prevent the false advertisement of foods, drugs, and cosmetics, and for other purposes." The powers which this bill, if enacted, would convey upon the Secretary of Agriculture, and which would of necessity in practice be delegated by him to subordinates of varying degree, would vest in the Secretary powers bordering on those of an autocrat, and charge him with responsibility for decisions wherein his opinion, once expressed, is to be given the finality of a court decree, in matters so extensive and complex as to challenge the capacity and wisdom of a Solomon. No reputable manufacturer, no honest advertiser, can take exception to the avowed purpose of that portion of the bill which seeks to protect the public against nefarious practices in respect to foods, drugs, and cosmetics, but there has been incorporated in the bill, evidently under that portion of the title expressed as "* * * and for other purposes" many provisions fraught with danger of great harm, not only to reputable, long-established businesses, but also the great body of salaried employees, whose living is wholly dependent upon the successful continuance in business of the institutions thus affected.

Obviously, this bill was conceived in an atmosphere of distrust and with much greater consideration for the apprehension of the miscreants, whose number, we believe it is admitted, is relatively small, than for due protection of reputable manufacturers and advertisers, whose number, we believe, admittedly is legion. This bill not only contains destructive provisions presently but vests the Secretary of Agriculture with unrestricted power to expand by regulations its provisions at his will to almost unlimited lengths, thus creating a situation wherein manufacturers and advertisers who arrange for compliance with the bill as promulgated may find themselves subject to prosecution for unintentional violation of new regulations contradictory or more inclusive than those theretofore pronounced.

Recognizing that the press of legislative matters which will demand your careful consideration immediately upon your return to Washington may make it difficult for you to retain all of the points which may be covered today in our discussion, we have, as a means of conserving your time and facilitating your consideration of the points involved, taken the liberty of setting forth hereinafter some of the provisions of the bill, together with comments and observations respecting the impracticability, injustice, and, we believe, dangerous effects or results likely to ensue if this bill, without substantial modification, should be enacted. We trust you may not judge us presumptuous in submitting this outline, which we hope may serve your convenience.

Section 3 provides—

"A food shall be deemed adulterated (b) (1) if any valuable constituent has been in whole or in part abstracted therefrom."

To cite one example of the application of this section, we suggest that a product such as Cream of Wheat, which is internationally sold as a breakfast cereal with a particular appeal as an infants' food, but which, of course, does not contain all of the wheat berry, would apparently be liable to classification as an adulterated food. If the provisions of the bill are not to be applied in accordance with their expressed language, and the sole and exclusive interpretations of what constitutes violations are to rest in the discretion of the Secretary and his assistants in the Department of Agriculture, manufacturers will never know definitely when they may be innocently violating some of the provisions of this bill.

Section 6 provides that a food or cosmetic shall be misbranded—

"If its labeling is in any particular false, or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetic."

You will note that the above section does not specify that the falsity be fraudulent or pertain to material matters. It constitutes an offense if the portion of the label alleged to be false pertains to any particular, or that even if by ambiguity or inference it creates a misleading impression. Sight must not be lost of the fact that if enacted this bill becomes a criminal statute, with severe and multiple penalties provided for violation. In criminal statutes, penalty for false statements is usually limited to a material matter. For example, to procure a conviction of perjury it must be shown that the false statement pertained to a material matter. Of course, no encouragement should be given to false statements relative to any matter, but this bill goes further by including any statements which "by ambiguity or inference creates a misleading impression." It covers typographical errors, unintentional mistakes, deliberate allegations of harmful misinterpretations, and also makes the advertiser wholly responsible for every possible type of mentality of the readers of his advertisement. An examination of the mail received by any radio advertiser who has made an offer of any kind over the radio stations of the country would at once demonstrate the impracticability of phrasing advertising in such manner as to avoid the possibility of misleading impressions being gained by some listeners. An offer simply and clearly stated will bring forth responses from all sections of the country so utterly inconsistent with the offer as to indicate the impossibility of avoiding misleading impressions on some people, regardless of the language chosen. Yet should anyone gain an impression wholly foreign to that intended by the advertiser to be conveyed, the advertiser becomes liable to severe punishment at the discretion of the Secretary of Agriculture under the powers vested in him by this bill.

Section 8 provides:

"A drug shall be deemed to be misbranded—(a) (1) if its labeling bears the name of any disease for which the drug is not a specific cure but is a palliative, and fails to bear in juxtaposition with such name and in letters of the same size and prominence a statement that the drug is not a cure for such a disease; * * *"

As a matter of fact, specific cures are known to medicine in only a few cases, and even these few cannot be considered specific cures in all cases. Rarely is any nationally advertised packaged medicine offered as a specific cure. It is offered usually for the relief of pains, distress or discomfort, or to assist Nature in avoiding certain diseases. To recognize how inclusive this provision is, let us quote the definition of disease—"any departure from, failure in, or perversion of normal physiological action in the living constitution or integrity of the living organism." Section 8 would therefore appear to prohibit the advertising of aspirin for the treatment of headaches, since under the above description headaches become a disease, unless there were printed conspicuously on the label of the aspirin package the words "Not a Cure." Simple salves for skin eruptions

and numerous other instances suggest themselves as indicating the drastic nature of this section.

Section 8 (a) further provides that a drug shall be deemed misbranded:

"(2) If its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion."

It is doubtful that the most sanguine reputable physician allied with any branch of medical thought, would venture the hope that there could ever be general agreement of medical opinion. Yet the advertiser may be adjudged guilty of crime if by "ambiguity or inference" his cartons, labels, or direction pamphlets, bear any representation "contrary to the general agreement of medical opinion." Medicine is not an exact science. Its progress to date owes much to the conflict of opinions among its practitioners, and there is today wide variation between the opinions of different schools of medicine among which are allopaths, homeopaths, eclectics, and osteopaths.

In *Eckman's Alterative* v. *United States* (239 U.S. 510), the Supreme Court of the United States held:

"* * * Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners. It was plainly to leave no doubt upon this point that the words 'false and fraudulent' were used."

In a case, *American School of Magnetic Healing* v. *McAnnulty* (187 U.S. 94), the Supreme Court held:

"As the effectiveness of almost any particular method of treatment of disease is, to a more or less extent, a fruitful source of difference of opinion, even though the great majority may be of one way of thinking, the efficacy of any special method is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud."

The Supreme Court of Arkansas, in *Green* v. *Blanchard* (138 Ark. 137), said:

"It is well known that the different schools of medicine, and even of dentistry, have widely divergent views as to the treatment of certain diseases."

The Supreme Court of California said, in *Hewitt* v. *Board of Medical Examiners* (148 Calif. 590):

"It is a matter of common knowledge that each school of medicine is governed in the treatment of diseases and injuries by rules and principles and practices in material respects fundamentally and essentially different, the adherents of each implicitly believing that the eradication or alleviation of diseases can be only successfully attained under the peculiar principles and practices of the particular school to which he belongs; that the successful treatment of a particular disease under radically different principles of medicine practiced by another school cannot be attained."

Obviously, therefore, a manufacturer whose formula and labeling may have been developed with the aid of the most reputable physicians practicing in his community, may have shipments of his goods seized by the Secretary of Agriculture because the latter has decided that by inference or ambiguity the labeling or advertising bore representations contrary to what he (the Secretary) and his academic advisers considered to be the "general agreement of medical opinion."

Section 8 (3) provides further that a drug shall be deemed to be misbranded:

"If * * * its label fails to bear * * * (2) the name and quantity or proportion of each medicinal or physiologically active ingredient thereof * * *."

This, of course, means complete formula disclosure and would amount to a confiscation of highly valuable trade assets without according any real or tangible benefit or protection to the public. It would appear that if the sole purpose of the framers of this legislation was protection of the public, that provision should have been made for registration or filing of a copy of the formula with the Secretary of Agriculture with proper provisions for preserving the secrecy thereof. Most formulas are technical and convey no understandable meaning to the public, outside of chemists, physicians, and pharmacists. Disclosure, however, would invite and encourage imitations, counterfeits, and infringements of reputable and proved products. The protection now afforded the public in the selfish desires of established companies to protect huge investments in well-known trade marks through the maintenance of various sorts of production and quality control, constitute the best safeguard which can be offered the public. Disclosure of the formulas so that irresponsible individuals with no investment in trade marks or names to protect, with questionable financial responsibility, and spurred by the opportunity to produce hastily and without control spurious products resembling those produced by established manufacturers, would result in injustice

to the established manufacturers and serve to endanger the public. The bill does not reach drug bootleggers and counterfeiters engaged in intrastate business.

Section 8 (e) (2) further provides:

"* * * The Secretary is hereby authorized to prescribe by regulations requirements for such further information on the label of such drug as he may deem necessary to protect the public health."

This certainly is an "open-end" provision which can be expanded to any extent and at any time that the Secretary, or in practice his subordinates, may deem necessary any provisions not now contained within this bill. Many labels and cartons are so small as to render it difficult to display the requirements as to contents, place of manufacture, formula, "complete and explicit directions for use", various warnings, and the declarations specifically required by other sections of this bill.

Section 12 provides:

"(a) Whenever the Secretary finds that the distribution in interstate commerce of any class of food, drugs, or cosmetics may, by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health, and such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he is authorized, after notice and hearing, to make such regulations governing the conditions of manufacture, processing, or packing as he deems necessary to protect the public health, and requiring manufacturers, processors, and packers of such class of articles to hold a permit conditioned on compliance with such regulations."

Further provisions of the bill authorize the Secretary to suspend any permit if it is found that any of the conditions of the permit have been violated. And, a manufacturer whose permit has been suspended is guilty of a violation of the act if he ships any goods until and unless the Secretary reinstates the permit.

Here bureaucracy attains its apex. The Secretary, not being satisfied with the power and control over the manufacture of foods, drugs, and cosmetics which he would have under the other provisions of this bill, is authorized by this section to regiment the industries into classes, to make such regulations covering the conditions of manufacture as he alone deems necessary to protect the public health, and to require manufacturers in each class to hold a permit which is conditioned on his being satisfied that the conditions which he himself has laid down have not been violated.

In other words, the Secretary—in practice, a bureau chief under him—is given the sole discretion to determine: (1) Whether any class of food, drugs, or cosmetics may be manufactured only under a permit; (2) under what conditions a permit will be granted; (3) when the permit will be suspended; and (4) when, if at all, the permit will be reinstated.

And, in addition, if in the exercise of this extraordinary power he suspends a permit, he can cause the goods of the manufacturer to be seized or the manufacturer to be indicted. This, it is readily seen, is more than extraordinary power. It is just a little short of Government ownership—ownership without any risk of business losses.

Section 21 provides:

"* * * The Secretary shall cause to be disseminated such information regarding any food, drug, or cosmetic as he deems necessary in the interests of public health and for the protection of the consumer against fraud."

This places in the hands of the Secretary—or his assistants—another dangerous power. Dissemination of any condemnatory information by the Secretary would be interpreted at once by the public as a conviction of the manufacturer. No provision is made in this portion of the bill that the Secretary shall first be required to give notice or hold hearings or disseminate such information after judicial judgment has been rendered. This power is given him in another portion of section 21. The above-quoted portion extending his powers to disseminate information which he "deems necessary" in the interest of public health, before trial, without notice, and regardless of what the manufacturer or advertiser has done to assure his compliance with the law. It is discretionary with the Secretary—or, in practice, a subordinate bureau chief—to determine (1) what information shall be disseminated, (2) when it shall be disseminated, (3) how it shall be disseminated, and (4) to whom it shall be disseminated—all without prior notice to manufacturers, distributors, or dealers affected, and without later compensation for damages unjustly caused them.

Section 23 (c) provides:

"Hearings authorized or required by this act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose. The findings of fact by the Secretary shall be conclusive, if in accordance with law,"

In practice, the Secretary or his subordinate actually establishes the law by making his findings conclusive. They are not subject to review by court, or jury, and rules of evidence do not apply in hearings. The result of this provision clearly establishes the Secretary of Agriculture as legislator, inspector, administrator, prosecutor, judge, and jury.

Perhaps one of the most objectionable features of this bill is that it defines in broad general terms certain spheres of authority and then authorizes a Government officer, by regulations of his own creation, to expand and elaborate (1) the legislative provisions of the bill; (2) the executive powers and functions; and (3) the judicial powers and offices. Further, it denies to persons engaged in private business the constitutional guarantees of due process of law and freedom from governmental oppression.

We direct your attention to the following provisions, which appear on pages 10 and 11 of the November 23, 1933, issue of the Printers' Ink Weekly, which epitomize the objections to the bill, and offer suggestions for revisions, which would meet the requirements of the honest merchandiser and seemingly not encounter too great opposition from the sponsors of the bill:

"1. The advertising industry will object to leaving such vague questions about advertising appeal as would be implied in inference and ambiguity, to a bureaucrat to decide. These should be decided only by the industry itself, when feasible at all. The administration, while nominally under control of the Secretary of Agriculture, would be actually carried out by a civil service employee. Thus would be built up a continuing bureaucracy.

"2. The publishers and advertising agencies will seek a definite exemption from liability in all cases unless they decline to give the Government information in their possession regarding the advertiser and his location.

"3. Damning an advertisement of a specific by indicating in bold type that it is not a cure, is too much of an advertising handicap. The same thing can be conveyed in clear and unmistakable ways without such a repelling signboard.

"4. Prohibiting any advertisement statement that a specific has any effect upon a list of well-known ailments seems as unreasonable as to prohibit a physician from prescribing for them. This should at least be limited to curative effect.

"5. Basing judgment as to the effects of a specific upon any ailment, upon general agreement of medical opinion, is too vague even for physicians to abide by. A much more effective criterion would be scientifically correct test.

"6. The same would be true of any self-medication. The Secretary of Agriculture should not have the power to determine what is safe or unsafe as a matter of personal opinion. This should always be based upon tests by those capable of making them. If it is right in the law to assure a proper hearing and notice of hearing before criminal prosecurion, this should also be applied to civil prosecution and to libel or seizure.

"7. Seizure should be limited to cases of emergency where public health is definitely menaced and prompt action is a factor.

"8. Penalties should not be inflicted upon advertisers for an innocent infraction of the law, and no penalty should apply until after the offender has been warned, as far as advertising copy is concerned.

"9. All material rulings by the Secretary, aside from administrative routing, should be subject to court review.

"10. There should be no unfavorable publicity given to a product or to an advertiser by the Secretary until after such product, or advertiser, has been condemned either by admission or by due process of law.

"11. United States attorneys should not be compelled by the law to proceed at the mere direction of the Secretary, without evidence being submitted satisfactory to the Department of Justice.

"12. No officer or employee of a corporation violating the law should be personally punished, unless personally responsible as having authorized, ordered, or performed such acts.

"13. Government inspectors, even in voluntary service, should not be paid by the advertiser, but by the Government itself, at least in major part; such inspection being instituted essentially for the protection of the public.

"14. It might be better to amend the original Food and Drugs Act without repealing it, instead of having a whole new statute, as such repeal might deprive the food and drug industry of a long series of court decisions under the act protective of them and also clarifying their rights.

"15. The bill frequently uses the words 'may be' in connection with 'dangerous to health.' This is too wide open and should be limited to the factual statement, 'is dangerous.'

"16. Where the rights of the advertiser are found to be invaded, the Secretary should be directed to grant relief, and not merely be authorized to afford it.

"No proprietary formulas should be publicly revealed, as that might destroy property in them, costing millions to build up; at most, such formulas should be confidentially furnished to the Secretary for his own information. Such detailed direction as to order of ingredients in a product might seriously handicap the producer in substituting materials of equal value because of current price.

"18. The clause referring to ambiguity and inference should be stricken out. This in its present form is a wide-open invitation to invasion.

"19. Everything in the bill relating to advertising should be clean-cut and specific. Advertisers should know in advance what they can and cannot do."

In conclusion please be assured that we—and we believe we are safe in saying that all reputable manufacturers and advertisers—are in full accord with the purpose of protecting the public against every form of business chicanery. All enlightened business men recognize that aside from any altruistic motivation, the elimination of unethical business practices is highly important, purely from a standpoint of profits, if honest merchandise and honest advertising are to receive proper recognition from the public.

We pledge our earnest endeavor to suitable legislation for this purpose, whether it be the Copeland bill, shorn of those provisions which we deem dangerous and unwarranted, amendments to the existing law, or other legislation.

We thank you most sincerely for your courtesy in conferring with us in this matter.

Respectfully submitted.

MERRILL HUTCHINSON,
For a Group of Associates.

MEMORANDUM CONCERNING THE PROPOSED FOOD AND DRUG ACT PREPARED BY A GROUP OF FACULTY WOMEN OF THE UNIVERSITY OF CALIFORNIA INTERESTED IN CONSUMERS' PROBLEMS

This group feels that a new food and drug act such as that presented in bill 1944 in the Senate of the United States is as a whole highly desirable. This group especially endorses—

(1) Provisions which subject advertising to the same control as labels;

(2) Provisions which require that the active constituents and amounts of pharmaceutical preparations be stated;

(3) Provisions which concern the prohibition of false advertising;

(4) Provisions which provide for control of manufacture, sale, and advertising of cosmetics;

(5) Provisions which provide for the adoption of specific standards for canned goods;

(6) Provisions which provide for a better control of poisonous foods.

It seems, however, that the wording of the provisions of the bill should be more clear and specific. For instance, in section 8, part b, it is somewhat difficult to ascertain from reading the bill whether it is the intent of the proposer that all drugs listed as narcotics should be sold only on physicians' prescription subjected to the same control as that imposed by the Harrison Narcotic Act for opiates—or merely that the active constituents or preparations containing any one of the listed narcotics shall be clearly stated on the label together with the possible effects. In the latter case we are entirely in sympathy with the act. In the former case, however, we feel that the list of drugs is entirely too inclusive in that it would impose an increase of, in some case, 500 to 600 percent in the cost of necessary and probably harmless drugs for the treatment of epilepsy and other chronic diseases.

We believe, in the case of canned foods, that not only should there be definite grades but that these grades should specifically be placed on the label and what they mean made clearly evident to the purchaser.

We feel that the increasingly severe penalties for the violation of the provisions controlling advertising are highly desirable. We are somewhat in doubt as to the sufficiency of the provision for control of training and qualifications of supervisors and administrators of the new bill. A training in the technical aspect of

foods, drugs, and cosmetics would seem to be as important as legal or political qualification.

We are also in doubt as to the disinterestedness of inspectors paid even indirectly by manufacturing concerns and doubt the wisdom of plunging food manufacture and control into such a bureaucratic maze as is suggested by section 22 of the proposed act. Some licensing system, however, for manufacturers suggests itself as a means of insuring that there be adequate technical training and care in the production of foods, drugs, and cosmetics.

It would be well to provide for a series of Government (Federal) bulletins which would report upon the most sought-after foods, drugs, and cosmetics—honestly, either favorably or unfavorably as investigation would require.

We do not wish you to consider that we feel that we have given you a complete résumé of all the provisions in the bill which should be altered in the direction of clearness. For the sake of brevity, however, we are sending only this memorandum which we will be glad to supplement if it seems desirable.

Any measures which serve to protect the consumer and make it impossible for him to tell what he is buying and to depend upon the truth of claims set forth in advertising, labels, or any literature pertaining to products needed for his daily living, should be of distinct value. This group therefore recommends the passage of this bill with the alterations as previously indicated.

We, as individuals, have studied the proposed act and have drawn up the preceding memorandum.

Agnes Fay Morgan, professor of household science; Florence A. Armstrong, assistant professor of household science; Ruth Okey, associate professor of household science; Emid A. Bunting, assistant professor of economics; Frances B. Peixott, professor of social economics; Harriet G. Eddy, assistant professor of agricultural extension; May Secrest, assistant State home demonstration leader; Mary F. Patterson, associate professor of household art and design; Lila M. O'Neale, associate professor of household art; Irene Sanborn Hall, instructor in household science.

Resolution Adopted by the North Central States Association of Food, Dairy, Drug, and Feed Officials, 1933

Whereas the enforcement of the Federal Food and Drugs Act has revealed many deficiencies in its provisions through which many serious abuses of the public health and the consumer's purse have arisen; and

Whereas the Food and Drug Administration of the United States Department of Agriculture with the approval of the President of the United States has prepared a bill which was introduced in Congress by Senator Copeland as Senate bill 1944, which is designed to correct these abuses by strengthening and extending the present law; and

Whereas the officials of the North Central States Association have used their best efforts in safeguarding the purity and truthful labeling of foods and drugs in their respective states: Therefore be it

Resolved, That the North Central States Association endorse Senate bill 1944 and that every effort be made to secure the passage of this bill in the forthcoming session of Congress.

Approved.

Guy G. Frary,
State Chemist, South Dakota.

Resolution Adopted by the North Central States Association of Food, Dairy, Drug, and Feed Officials, 1933

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Approved.

South Dakota Department of Agriculture,
T. O. Ronayne, *Chief Inspector.*

Resolution Adopted by the North Central States Association of Food, Dairy, Drug, and Feed Officials, 1933

Whereas the enforcement of the Federal Food and Drugs Act has revealed many deficiencies in its provisions through which many serious abuses of the public health and the consumer's purse have arisen; and

Whereas the Food and Drug Administration of the United States Department of Agriculture with the approval of the President of the United States has prepared a bill which was introduced in Congress by Senator Copeland as Senate bill 1944, which is designed to correct these abuses by strengthening and extending the present law; and

Whereas the officials of the North Central States Association have used their best efforts in safeguarding the purity and truthful labeling of foods and drugs in their respective States: Therefore be it

Resolved, That the North Central States Association endorse Senate bill 1944 and that every effort be made to secure the passage of this bill in the forthcoming session of Congress.

Approved.

C. S. Ladd,
North Dakota Food Commissioner and Chemist.

Resolution Adopted by the North Central States Association of Food, Fairy, Drug, and Feed Officials, 1933

Whereas the enforcement of the Federal Food and Drugs Act has revealed many deficiencies in its provisions through which many serious abuses of the public health and the consumer's purse have arisen; and

Whereas the Food and Drug Administration of the United States Department of Agriculture with the approval of the President of the United States has prepared a bill which was introduced in Congress by Senator Copeland as Senate bill 1944, which is designed to correct these abuses by strengthening and extending the present law; and

Whereas the officials of the North Central States Association have used their best efforts in safeguarding the purity and truthful labeling of foods and drugs in their respective States: Therefore be it

Resolved, That the North Central States Association endorse Senate Bill 1944 and that every effort be made to secure the passage of this bill in the forthcoming session of Congress.

Approved.

W. H. McGaffin, *Acting Director.*

Resolution Adopted by the North Central States Association of Food, Dairy, Drug, and Feed Officials, 1933

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Whereas, the officials of the North Central States Association have used their best efforts in safeguarding the purity and truthful labeling of foods and drugs in their respective States: Therefore be it

Resolved, That the North Central States Association endorse Senate bill 1944 and that every effort be made to secure the passage of this bill in the forthcoming session of Congress.

Approved.

EARLE G. BROWN, M.D.,
Secretary and Executive Officer Kansas State Board of Health.

RESOLUTION ADOPTED BY THE NORTH CENTRAL STATES ASSOCIATION OF FOOD, DAIRY, DRUG, AND FEED OFFICIALS, 1933

Whereas, the enforcement of the Federal Food and Drugs Act has revealed many deficiencies in its provisions through which many serious abuses of the public health and the consumer's purse have arisen; and

Whereas, the Food and Drug Administration of the United States Department of Agriculture with the approval of the President of the United States has prepared a bill which was introduced in congress by Senator Copeland as Senate bill 1944, which is designed to correct these abuses by strengthening and extending the present law; and

Whereas, the officials of the North Central States Association have used their best efforts in safeguarding the purity and truthful labeling of foods and drugs in their respective states: Therefore, be it

Resolved, That the North Central States Association endorse Senate bill 1944 and that every effort be made to secure the passage of this bill in the forthcoming session of Congress.

Approved.

HENRY HOFFMAN, Jr.,
Minnesota.

RESOLUTION ADOPTED BY THE NORTH CENTRAL STATES ASSOCIATION OF FOOD DAIRY, DRUG, AND FEED OFFICIALS, 1933

Whereas the enforcement of the Federal Food and Drugs Act has revealed many deficiencies in its provisions through which many serious abuses of the public health and the consumer's purse have arisen; and

Whereas the Food and Drugs Administration of the United States Department of Agriculture with the approval of the President of the United States has prepared a bill which was introduced in Congress by Senator Copeland as Senate bill 1944, which is designed to correct these abuses by strengthening and extending the present law; and

Whereas the officials of the North Central States Association have used their best efforts in safeguarding the purity and truthful labeling of foods and drugs in their respective States: Therefore be it

Resolved, That the North Central States Association endorse Senate bill 1944 and that every effort be made to secure the passage of this bill in the forthcoming session of Congress.

Approved.

E. L. REDFERN,
Chief Chemist, Department of Agriculture.

BRIEF OF E. J. LEVER, PRESIDENT COOPERATIVE DISTRIBUTORS, INC.

As a National Cooperative Association owned and operated by ultimate consumers for their protection in a profit-motivated market, we believe that no permanent and continuous protection can be secured for consumers unless and until consumers are organized to supply themselves with the necessities of life and thereby remove the major problems this bill is intended to regulate.

Since complete consumer organization and social ownership is not yet attained, we are in favor of the proposed bill in spite of its limitations.

The time has arrived when Congress should provide some real protection to wage earners, farmers, and salaried people, as consumers of foods and drugs, in addition to their general protection as producers in industry.

The sale of goods or services to consumers is the only thing that gives those industries economic value. In the absence of consumer control, if private industry will not adequately, safely, and equitably supply consumer needs, the principle of governmental regulation must be applied. Experience in other fields proves that Government regulation tends to protect the consumers' safety, health, and income.

II

Opponents of the bill object to several of its provisions, especially those parts which empower the Secretary of Agriculture, a Cabinet officer, to regulate the future standards and conduct in the manufacture, advertisement, and sale of those products. But the law of 1906, which this is to replace, does specify the methods of manufacture and sale of foods and drugs. It is the circumvention of the provisions of that act that this bill is intended to meet, since processors and sellers have violated all human decency in their operations for private gain, of which convincing evidence is presented by the sponsors and other supporters of the bill.

All consumers need such protection. A minority have the means for proper medical care and thereby avoid the necessity of self-medication to a large extent. But, for lack of income, proper medical care is, however, not available to the overwhelming majority of workers, farmers, and their families. They are, therefore, compelled to fall back on self-medication. This tragic state of affairs makes them easy victims of unscrupulous manufacturers, advertisers, and vendors of adulterated foods and of quack medicines and cure-alls. This bill will afford some measure of protection to these millions of consumers, whose welfare should be the Government's greatest concern.

No subtlety is required to realize that possible loss of profits is the greatest fear of opponents of this bill—not the possible loss of jobs of their employees.

The issue is presented squarely to Congress whether it shall be possible loss of profit for the few, or loss of health and even life to millions of consumers.

Respectfully submitted.

COOPERATIVE DISTRIBUTORS, INC.,
E. J. LEVER, *President.*
J. J. SCHALET, *Secretary.*

TRI-STATE PACKERS' ASSOCIATION, INC.,
Easton, Md., December 16, 1933.

Senator ROYAL S. COPELAND,
United States Senate Office Building, Washington, D.C.

MY DEAR SENATOR COPELAND: We wish to get before you and the subcommittee which conducted hearings on Senate bill 1944 the fact that the Tri-State Packers' Association is heartily in favor of the bill as it relates to canned foods.

We make no pretense whatever on passing judgment on the bill as it relates to drugs and cosmetics. At our twenty-ninth annual convention held in Philadelphia this week the following resolution pertaining to the statement of grades of quality on canned foods labels was unanimously passed.

"*Resolved*, That this association go on record as favoring the use by its members of more descriptive and informative labels and that we particularly recommend the use of grade designations A, B, and C as now defined feeling that not until the consumer can buy our products intelligently and with confidence will this industry enjoy the increased consumption and greater consumer preference to which it is entitled by the high quality of its products."

We are particularly anxious to get this action of the Tri-State Association before you in view of the opposition to grades of quality above substandard registered with your committee by the National Canners' Association. In fact, many of their members are now labeling their products with the grade designations "A", "B", and "C." In fact, it is customary in quoting canned fruits and vegetables to make the quotatoins by grades. Always quotations are designated at certain prices for Fancy, Choice or Extra Standard, and Standard grade. Insofar as groups of canners report sales, shipments, or stocks of canned foods these reports are invariably by grades. Confirming this statement I am enclosing a few sample reports. This all indicates that no hardship would be placed upon the canning industry by such regulations or requirements as might be brought about through the proposed bill

Very truly yours,

F. M. SHOOK, *Field Secretary.*

ASSOCIATION OF NEW YORK STATE CANNERS, INC., ROCHESTER, N.Y.

New York stocks of green and wax beans, July 1, 1933

Can size	Grade	Green beans		Wax beans	
		Sold, not shipped	Unsold	Sold, not shipped	Unsold
55	Whole, fancy	0	0	0	0
55	Whole, extra standard	0	0	0	0
55	Whole, standard	0	0	0	0
55	Cut, fancy	42	871	562	497
55	Cut, extra standard	0	0	0	0
55	Cut, standard	0	0	0	0
	Total	42	871	562	497
1	Whole, fancy	0	4	0	82
1	Whole, extra standard	0	0	0	0
1	Whole, standard	0	0	0	0
1	Cut, fancy	47	1,371	77	2,815
1	Cut, extra standard	19	285	13	841
1	Cut, standard	0	0	0	0
	Total	66	1,660	90	3,738
2	Whole, fancy	17,304	17,233	281	1,421
2	Whole, extra standard	23	728	0	361
2	Whole, standard	0	0	0	0
2	Cut, fancy	11,934	20,909	884	7,642
2	Cut, extra standard	3,337	3,690	496	1,406
2	Cut, standard	108	79	0	33
	Total	32,706	42,639	1,661	10,863
[1]10	Whole, fancy	228	1,005	1	9
10	Whole, extra standard	55	290	0	0
10	Whole, standard	0	200	0	0
10	Cut, fancy	807	5,640	251	3,147
10	Cut, extra standard	403	1,185	46	328
10	Cut, standard	465	73	120	0
	Total	1,958	8,393	418	3,484

[1] All no. 10s as dozens.

Wisconsin Canners Association sales report for period Dec. 2 to Dec. 9, 1933, 26 companies reporting

ALASKA PEAS

Can size	Number of cases	Price	Delivered or factory
Fancy no. 2 sieve:			
2	24	$1.65	Factory.
2	1,100	1.50	Do.
Near fancy no. 2 sieve:			
1	75	1.05	Do.
Near fancy no. 3 sieve:			
2	2,000	1.25	Do.
Extra standard no. 1 sieve:			
2	50	1.35	Do.
Extra standard no. 2 sieve:			
2	1,140	1.25	Do.
2	1,250	1.22½	Do.
Extra standard no. 3 sieve:			
1	100	$0.85	Delivered.
1	25	.85	Factory.
2	1,000	1.25	Do.
2	630	1.20	Do.
2	1,550	1.10	Do.
2	2,125	1.00	Do.
2	3,000	.90	Do.
Standard no. 4 sieve:			
1	215	.75	Do.
2	100	1.10	Do.
Standard, ungraded:			
2	74	1.10	Do.

BEETS

Fancy:			
2, diced	357	$0.80	Factory.
2½, cut	75	.85	Do.
Fancy—Continued			
2½, cut	25	$0.95	Factory
10, cut	10	3.25	Do.

CORN

Fancy; C.G.:			
2	200	$1.00	Factory.
Extra standard:			
10, Crosby	10	5.00	Do.
Standard:			
2, N.G.	1,120	$0.75	Factory
10, Crosby	750	4.50	Do.
10, Evergreen	300	3.75	Do.

Wisconsin Canners Association sales report for period Dec. 2 to Dec. 9, 1933, 26 companies reporting—Continued

KRAUT

Can size	Number of cases	Price	Delivered or factory
Fancy:			
Gallons	90	$13.50	Factory.

SWEET PEAS

Can size	Number of cases	Price	Delivered or factory
Fancy no. 2 sieve:			
2	12	$1.25	Delivered.
Fancy no. 3 sieve:			
1	15	.80	Factory.
Fancy no. 5 sieve:			
1	100	.90	Do.
2	250	1.22½	Do.
Fancy no. 6 sieve:			
2	25	1.20	Do.
Extra standard no. 3 sieve:			
10	193	6.75	Do.
Extra standard no. 4 sieve:			
1	500	$0.77½	Factory
2	286	1.10	Do.
Standard no. 4 sieve:			
1	50	.75	Do.
Standard no. 5 sieve:			
2	1,081	1.10	Do.
Standard no. 6 sieve:			
2	1,000	1.10	Do.

WAX BEANS

Fancy:			
2, 3 whole	10	$1.30	Factory.
10, 4 whole	10	5.75	Do.
8-ounce, cut	5	.65	Do.
2, cut	1	1.10	Do.
Extra standard:			
2, 4 cut	150	$0.90	Factory
2, 5 cut	150	.85	Do.
Standard:			
2, 5 cut	1	.85	Do.

GREEN BEANS

Fancy:			
2, 1 whole	16	$1.75	Factory.
2, 2 whole	1	1.40	Do.
2, 3 whole	25	1.30	Do.
8-ounce, cut	5	.65	Do.
2, cut	1	1.10	Do.
Extra standard:			
2, 4 cut	15	$1.00	Factory
Do	150	.90	Do.
Standard:			
2, cut	1,000	.77½	Do.
2, 5 cut	1	.85	Do.
10, 5 cut	25	4.00	

Summary of confirmations

	Cases
Alaskas	14,458
Sweets	3,562
Wax beans	327
Green beans	1,239
Beets	467
Corn	2,380
Kraut	90
Total confirmations of above	22,523

STATEMENT WITH REFERENCE TO REVISED BILL, S. 2000

As a result of the hearings early in December on the proposed revision of the Food and Drugs Act, Senator Copeland introduced a new bill embodying sweeping changes in the measure. These changes have not detracted from the

consumer protection the original bill sought to afford, but they remove the causes for apprehension so generally felt by reputable manufacturers whose products would be regulated by the law.

One of the principal points of difference between the old and new bills is the extent to which authority is lodged in the hands of administrative officers. In Senator Copeland's draft the delegation of regulation-making power is confined to those few instances where the problems are so complex and so changing with scientific progress that adequate protection of the public cannot otherwise be offered. Even in these instances the administrative officers cannot act independently, but are subject to the check of nonpartisan committees of scientists whose members are affiliated with neither the enforcing agency nor the regulated industries. Moreover, definite provision is made for court review of regulations.

Senator Copeland's revision omits references to "inference and ambiguity" in defining offenses, which aroused great opposition to the old bill, but in clarifying these and other provisions there has been no weakneing of the measure. It also omits the sweeping provision requiring full formula disclosure on all proprietary drugs, the advantage of which to consumers has been questioned with good reason, and substitutes for it requirements for label declaration of certain potent ingredients, coupled with label warnings against unsafe methods of administration.

Instead of prohibiting therapeutic claims for a drug if they are contrary to the general agreement of medical opinion, such claims are declared as misbranding if they are not supported by substantial medical opinion or by demonstrable scientific facts. The requirement that a palliative be labeled as not a cure has been changed to compel labeling to show how the palliation is effected.

In these and all other possible ways the bill has been made clearer and more definite, without the sacrifice of any provision essential to public welfare. The section on voluntary inspection service has been deleted, as well as that authorizing investigations through the medium of the Federal Trade Commission Act, since these sections had caused great apprehension, and protection of consumers has been accomplished through other provisions in the bill.

An important addition to the measure authorizes the enforcing agency to accept plans of representative advertising associations for the self-regulation of advertising practices. But this does not relieve the enforcing agency from any of its responsibilities.

"The bill as it now stands", Senator Copeland says, "should receive the support of all consumers. It should likewise receive the endorsement of that great majority of the industries affected which is doing a reputable business. It is fair to all concerned."

The new bill, S. 2000, follows:

[S. 2000, Seventy-third Congress, second session]

A BILL To prevent the manufacture, shipment, and sale of adulterated or misbranded food, drink, drugs, and cosmetics, and to regulate traffic therein; to prevent the false advertisement of food, drink, drugs, and cosmetics; and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Food and Drugs Act."

DEFINITION OF TERMS

SEC. 2. As used in this Act, unless the context otherwise indicates—

(a) The term "food" includes all substances and preparations used for, or entering into the composition of, food, drink, confectionery, or condiment for man or other animals.

(b) The term "drug" includes (1) all substances and preparations recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, or National Formulary or supplements thereto; and (2) all substances, preparations, and devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations, other than food, and all devices intended to affect the structure or any function of the body.

(c) The term "cosmetic" includes all substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of, the person.

(d) The term "territory" means any territory or possession of the United States, including the District of Columbia.

(e) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, or between points within the same State or Territory but through any place outside thereof, and (2) commerce or manufacture within the District of Columbia or within any other territory not organized with a legislative body.

(f) The term "person" includes individual, partnership, corporation, and association.

(g) The term "Secretary" means the Secretary of Agriculture.

(h) The term "label" means the principal label or labels (1) upon the immediate container of any food, drug, or cosmetic, and (2) upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic.

(i) The term "labeling" includes all labels and other written, printed, and graphic matter, in any form whatsoever, accompanying any food, drug, or cosmetic.

(j) The term "advertisement" includes all representations of fact or opinion disseminated in any manner or by any means other than by the labeling.

ADULTERATED FOOD

SEC. 3. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance prohibited, or in excess of the limits of tolerance prescribed, by regulations as provided by sections 10 and 22; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth; or (5) if it is the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed of any poisonous or deleterious substance which may by contamination render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight in a deceptive manner, or reduce its quality or strength, or create a deceptive appearance.

(c) If it is confectionery and bears or contains any alcohol, resinous glaze, or nonnutritive substance except masticatory substances in chewing gum, coloring, and flavoring.

(d) If it contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by sections 10 and 22.

ADULTERATED DRUGS

SEC. 4. A drug shall be deemed to be adulterated—

(a) If it is dangerous to health under the conditions of use prescribed in the labeling thereof.

(b) If its name is the same as or simulates a name recognized in the United States Pharmacopœia, Homeopathic Pharmacopœia of the United States, or National Formulary, or in any supplement thereto, official at the time the drug is introduced into interstate commerce, or if it purports to be such a drug, and it (1) fails to meet the definition, formula, and description set forth therein, or (2) differs from the standard of strength, quality, or purity as determined by the tests or methods of assay set forth therein; except that whenever tests or methods of assay have not been prescribed therein or such tests or methods of assay as are prescribed are insufficient, the Secretary is hereby authorized to prescribe by regulations, as provided by section 22, tests or methods of assay for determining whether or not such drug complies with such standard. No drug shall be deemed to be adulterated under subdivision (2) of this paragraph if its label bears, in juxtaposition with the name of the drug, a statement indicating wherein its strength, quality, and purity differ from the standard of strength, quality, and purity set forth in the United States Pharmacopœia, Homeopathic Pharmacopœia of the United States, or National Formulary, as the case may be, or in any supplement thereto, official at the time the drug is introduced into interstate commerce, as determined by the tests or methods of assay applicable under this paragraph. Whenever a drug is recognized in both the United States Pharmacopœia and the Homeopathic Pharmacopœia of the

United States it shall be subject to the requirements of the United States Pharmacopœia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its identity or strength differs from, or its purity or quality falls below, that which its purports or is represented to possess.

(d) If any substance has been (1) mixed or packed therewith so as to reduce its quality or strength in a deceptive manner, or (2) substituted wholly or in part therefor.

ADULTERATED COSMETICS

SEC. 5. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to the user under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

(b) If it bears or contains any poisonous or deleterious ingredient prohibited, or in excess of the limits of tolerance prescribed, by regulations as provided by sections 10 and 22.

MISBRANDED FOOD, DRUGS, AND COSMETICS—GENERAL

SEC. 6. A food, drug, or cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular: *Provided*, That no drug shall be deemed to be misbranded under this paragraph because of any representation concerning any effect of such drug if that representation is supported by substantial medical opinion or by demonstrable scientific facts.

(b) If in package form it fails to bear a label containing: (1) The name and place of business of the manufacturer, packer, seller, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under subdivision (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) The Secretary is hereby authorized to promulgate regulations exempting from any labeling or packaging requirement of this Act food, drugs, and cosmetics, which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such articles are in conformity with the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(d) If any word, statement, or other information required on the label to avoid adulteration or misbranding under any provision of this Act is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily intelligible to the purchasers and users of such articles under customary conditions of purchase and use.

MISBRANDED FOOD

SEC. 7. A food shall be deemed to be misbranded—

(a) (1) If its container is so made, formed, or filled as to mislead the purchaser, or (2) if its contents fall below the standard of fill prescribed by regulations as provided by sections 11 and 22.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, except that no imitation shall be deemed to be misbranded under this paragraph if its label bears the word "imitation" in juxtaposition with and in type of the same size and prominence as the name of the food imitated.

(d) If it purports to be or is represented as a food for which a definition and minimum standard of identity have been prescribed by regulations as provided by sections 11 and 22, and (1) its label fails to bear the name of the food prescribed in the definition and minimum standard, or (2) it fails to conform to such definition and minimum standard.

(e) If it purports to be or is represented as a food for which standards of quality have been prescribed by regulations as provided by sections 11 and 22, and (1) its label fails to bear, if so required by the regulations, a standard of quality in such terms as the regulations specify, or (2) it falls below such standard.

(f) If it purports to be or is represented as a food for which no definition and minimum standard of identity has been prescribed by regulations as provided by

sections 11 and 22, and its label fails to bear (1) the common or usual name of the food, if any there be, and (2) the common or usual name of each ingredient such food bears or contains in order of predominance by weight; except that spices, flavors, and colorings, other than those sold as such, may be designated as spices, flavors, and colorings without naming each: *Provided*, That, to the extent that a statement on the label of each ingredient in order of predominance by weight is impracticable because of normal variations in ingredients or their quantities, usual to manufacturing or packing processes, reasonable variations from such order shall be permitted, and exemptions as to packages of assorted food shall be established, by regulations promulgated by the Secretary.

(g) If it is for special dietary uses, such as by infants or invalids or for other special nutritional requirements, and its label fails to bear, if so required by regulations as provided by section 22, statements concerning its vitamin, mineral, and other dietary properties which fully inform the purchaser as to its nutritional value.

MISBRANDED DRUGS

SEC. 8. A drug shall be deemed to be misbranded—

(a) If its labeling bears the name of any disease for which the drug is not a specific cure but is a palliative, and fails to bear a plain and conspicuous statement, so placed as to be readily observable where such name occurs, indicating that the drug is a palliative and how the palliation is affected.

(b) If it is for internal use by man and contains any quantity of any of the following narcotic or hypnotic substances: Alpha eucaine, barbital, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, morphine, opium, paraldehyde, peyote, sulphonmethane, or any narcotic or hypnotic derivative therefrom by actual or theoretical chemical reaction, and its label fails to bear the name and quantity or proportion of such substance or derivative in juxtaposition with the statement "Warning—May be habit forming." The Secretary is hereby authorized to designate by regulations, as provided by section 22, other substances possessing habit-forming narcotic or hypnotic properties, which substances shall thereafter be subject to the provisions of this paragraph.

(c) If it contains any quantity of the stimulant-depressant substances ethyl alcohol, ethyl ether, chloroform, or isopropyl alcohol; or the sedative substances acetanilid, acetphenetidin, amidopyrin, antipyrin, bromides, or hyascyamus; or the cumulative substances arsenic, atropine, digitalis, mercury, or strychnine; and its label fails to bear a statement of the name and quantity or proportion of such substance. The Secretary is hereby authorized to designate by regulations, as provided by section 22, other substances possessing stimulant-depressant, sedative, or cumulative properties, which substances shall thereafter be subject to the provisions of this paragraph.

(d) If its labeling fails to bear, plainly and conspicuously, complete and explicit directions for use: *Provided*, That where any requirement of this paragraph, as applied to any drug, is not necessary for the protection of the public health, the Secretary shall promulgate regulations, as provided by section 22, exempting such drug from such requirement.

(e) If its label fails to bear (1) such warnings as may be prescribed by regulations, as provided by section 22, against use in such pathological conditions or by children where its use is contraindicated and may be dangerous to health, or against unsafe dosage or methods of administration or application; and (2) the common or usual name of the drug, if any there be: *Provided*, That subdivision (2) of this paragraph shall not apply to drugs subject to paragraph (b) of section 4.

(f) If its name is the same as, or simulates, a name recognized in the United States Pharmacopœia, Homeopathic Pharmacopœia of the United States, or National Formulary or any supplement thereto official at the time such drug is introduced into interstate commerce, and it is not packaged and labeled as prescribed therein. Whenever a drug is recognized in both the United States Pharmacopœia and the Homeopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to such provisions of the Homeopathic Pharmacopœia of the United States and not those of the United States Pharmacopœia.

(g) If it has been designated by regulations, as provided by section 22, as a drug liable to deterioration, and is not packaged in such form or manner, or its label fails to bear a statement of such precautions, as such regulations require for the protection of public health.

(h) (1) If its container is so made, formed, or filled as to mislead the purchaser; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(i) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for any use on or within the body and its labeling fails to bear a statement of each such use and, plainly and conspicuously and in juxtaposition therewith, the method and duration of application necessary to kill all microorganisms in the vegetative or other active form with which it comes in contact when so used; except that no drug shall be deemed to be misbranded under this paragraph if its label bears a statement that it is a germicide, bactericide, disinfectant, or antiseptic for specific kinds of microorganisms only, and its labeling bears a statement of each purported or represented use and, plainly and conspicuously and in juxtaposition therewith, the conditions, including duration of application, under which the drug kills all such specific kinds of microorganisms in the vegetative or other active form with which it comes in contact when so used.

(j) If it purports to be or is represented as an inhibitory antiseptic for any use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body and its labeling fails to bear a statement of each such use and, plainly and conspicuously and in juxtaposition therewith, the method of application necessary to prevent the growth of all microorganisms with which it comes in contact during the time of such contact when so used.

FALSE ADVERTISEMENT

SEC. 9. (a) An advertisement of a food, drug, or cosmetic shall be deemed to be false if it is false or misleading in any particular relevant to the purposes of this Act regarding such food, drug, or cosmetic: *Provided*, That no advertisement shall be deemed to be false under this paragraph because of any representation concerning any effect of a drug if that representation is supported by substantial medical opinion or by demonstrable scientific facts.

(b) An advertisement of a drug shall also be deemed to be false if it contains the name of any disease for which the drug is not a specific cure but is a palliative and fails to contain a plain and conspicuous statement, so placed as to be readily observable where such name occurs, indicating that the drug is a palliative and how the palliation is effected.

(c) To discourage the public advertisement for sale in interstate commerce of drugs for diseases wherein self-medication may be especially dangerous, or patently contrary to the interests of public health, any advertisement of a drug representing it to have any effect in the treatment of any of the following diseases shall be deemed to be false: Albuminuria, appendicitis, arteriosclerosis, blood poison, bone diseases, cancer, carbuncles, cataract, chloecystitis, diabetes, diphtheria, dropsy, encephalitis, erysipelas, gall-stones, heart diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis, prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infections, smallpox, tuberculosis, tumors, typhoid, uremia, venereal diseases, and whooping cough; except that no advertisement not in violation of paragraph (a) or (b) of this section shall be deemed to be false under this paragraph if it is disseminated to members of the medical and pharmaceutical professions only or appears in the scientific periodicals of these professions, or if it is disseminated for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs: *Provided*, That whenever the Secretary determined that an advance in medical science has made any type of self-medication safe as to any of the diseases enumerated above, he shall promulgate regulations, as provided by section 22, exempting the advertisement of drugs having curative or therapeutic effect for such disease from the operation of this paragraph, subject to such conditions and restrictions as may be necessary in the interests of public health.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND COSMETICS AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 10. (a) If an added poisonous or added deleterious substance in or on food or cosmetics is or may be injurious to health, the Secretary is hereby authorized to promulgate regulations, as provided by section 22, prohibiting such added substance in or on any food or cosmetic, or establishing tolerances limiting the amount therein or thereon, for the protection of public health, taking into account the extent to which the use of such substance is required in the production

of such food or cosmetic and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary is hereby authorized to promulgate regulations, as provided by section 22, for the certification of coal-tar colors which are harmless and suitable for use in food.

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 11. For the effectuation of the purposes of this Act the Secretary is hereby authorized to promulgate regulations, as provided by section 22, fixing and establishing for any food (1) definitions and minimum standards of identity, and (2) objectively determinable standards of quality and fill of container: *Provided*, That the designation of such standards of quality shall, as far as consistent with public interest, follow prevailing trade nomenclature.

PERMIT FACTORIES

SEC. 12. (a) Whenever the Secretary finds that the distribution in interstate commerce of any class of food, drugs, or cosmetics may, by reason of conditions surrounding the manufacture, processing, or packing thereof, be injurious to health, and such injurious nature cannot be adequately determined after such articles have entered interstate commerce, and in such case only, he is authorized to promulgate regulations, as provided by section 22, governing the conditions of manufacture, processing, or packing necessary to protect the public health, and requiring manufacturers, processors, and packers of such class of articles to hold a permit conditioned on compliance with such regulations.

(b) The Secretary is authorized to issue such permits for such periods of time as he may by regulations prescribe and to make regulations governing the issuance and renewal thereof. The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The Secretary shall reinstate the permit whenever, after hearing and an inspection of the establishment, it is found that adequate measures have been taken to comply with and maintain the conditions of the original permit.

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

FACTORY INSPECTION

SEC. 13. (a) In order adequately to regulate interstate commerce in food, drugs, and cosmetics, and enforce the provisions of this Act, officers or employees duly designated by the Secretary, after first making reasonable request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter any factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed, or held for shipment in interstate commerce or are held after such shipment, or to enter any vehicle being used to transport such food, drugs, or cosmetics, in interstate commerce; and (2) to inspect such factory, warehouse, establishment, or vehicle and all equipment, finished and unfinished materials, containers, and labels there used or stored.

(b) The several district courts of the United States are hereby vested with jurisdiction to restrain by injunction, temporary or permanent, the shipment in interstate commerce or delivery after receipt in interstate commerce of any food, drug, or cosmetic from or by any factory, warehouse, establishment, or vehicle, designated in paragraph (a) of this section, if the owner, operator, or custodian thereof has denied to officers or employees duly designated by the Secretary permission, after reasonable request, so to enter and inspect such factory, warehouse, establishment, or vehicle and equipment, finished and unfinished materials, containers, and labels there used or stored. Whenever such permission is granted, the injunction issued pursuant to this paragraph shall be dissolved, or may be continued in force subject to such conditions governing the inspection as the court may order. Violation of any injunction issued pursuant to this paragraph may be summarily tried and punished by the court as a contempt. Such contempt proceedings may be instituted by order of the court or by the filing of an information by the United States attorney.

RECORDS OF INTERSTATE SHIPMENT

SEC. 14. For the purpose of enforcing the provisions of this Act, carriers subject to the Interstate Commerce Act, as amended (U.S.C., title 49), and other carriers engaged in interstate commerce, and persons receiving food, drugs, or cosmetics in interstate commerce, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee to have access to and to copy all records showing the movement in interstate commerce of any food, drug, or cosmetic, and the quantity, shipper and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a definite statement in writing specifying the nature or kind of food, drug, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.

INVESTIGATIONS AND INSTITUTION OF PROCEEDINGS

SEC. 15. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department of Agriculture or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary. To aid in securing compliance with the requirements of this Act, the Secretary is further authorized to accept plans for such selfregulation of advertising practices as tend to effectuate the purposes of this Act, when presented by associations or groups representative of their industries: *Provided*, That such plans shall not restrict the responsibilities and powers conferred upon the Secretary by this Act and shall not be designed to promote monopolies or eliminate or oppress legitimate enterprise.

(b) It shall be the duty of each United States attorney to whom the Secretary reports any violation for institution of criminal, libel for condemnation, or other proceedings under this Act, or to whom any health, food, or drug officer of any State or Territory, or political subdivision thereof, presents evidence satisfactory to the United States attorney of any such violation, to cause appropriate proceedings to be instituted in the proper courts of the United States without delay. All suits instituted under this Act shall be by and in the name of the United States.

(c) The Secretary shall, before reporting any violation of this Act to the United States attorney for institution of criminal proceedings thereunder, afford due notice and opportunity for hearing to interested parties in accordance with such regulations as the Secretary shall prescribe. The report of the Secretary to the United States attorney for the institution of criminal proceedings under this Act shall be accompanied by findings of the appropriate officers and employees, duly authenticated under their oaths. Nothing in this Act shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings violations of this Act of a minor formal character only whenever he believes that the purposes of the Act can best be accomplished by a suitable notice or warning.

SEIZURE

SEC. 16. (a) Any article of food, drug, or cosmetic in interstate commerce that is adulterated or misbranded or that has been manufactured, processed, or packed in a factory or establishment, the operator of which did not, at the time time of manufacture, processing, or packing, hold a valid permit if so required by regulations under section 12, shall be liable to be proceeded against while in interstate commerce or at any time thereafter on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. The article shall be liable to seizure (1) by process pursuant to the libel, or (2) if a chief of station or other officer of the Food and Drug Administration, duly designated by the Secretary, has probable cause to believe that the article is so adulterated as to be imminently dangerous to health, then, and in such case only, by order of such officer, issued under his oath of office, particularly describing the article to be seized, the place where located, and the officer or employee to make the seizure. In case of seizure pursuant to any such order, the jurisdiction of the court shall attach upon such seizure. Any article seized pursuant to any such order shall thereupon be promptly placed in the custody of the court and a libel of information shall be promptly filed for condemnation thereof.

(b) When, upon the trial of any cause instituted pursuant to paragraph (a) subdivision (2) of this section, judgment is rendered for the claimant, but it appears to the court that there was reasonable cause for the seizure, the court shall cause a proper certificate thereof to be entered and no officer or employee of the United States shall be liable to suit or judgment by reason of the seizure of the goods or the institution of such proceedings.

(c) The court may, by order at any time before trial, allow any party to a condemnation proceeding to obtain a representative sample of the article seized.

(d) Any article of food, drug, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article of food, drug, or cosmetic shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the party obtaining release of the article under bond. Any article condemned by reason of the manufacturer, processor, or packer not holding a valid permit when so required by regulations under section 12 shall be disposed of by destruction.

(e) The proceedings in cases under this section shall conform, as nearly as may be, to the proceedings in admiralty; except that either party may demand trial by jury of any issue of fact joined in any such case.

(f) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

PENALTIES

SEC. 17. (a) The following acts are hereby prohibited:

(1) The introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded.

(2) The adulteration or misbranding of any food, drug, or cosmetic in interstate commerce.

(3) The receipt in interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded and the delivery or proffered delivery thereof in the original unbroken package for pay or otherwise.

(4) The dissemination of any false advertisement by radio broadcast, United States mails, or in interstate commerce for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics.

(5) The dissemination of a false advertisement by any means for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics in interstate commerce.

(6) The introduction into interstate commerce of any food, drug, or cosmetic if the manufacturer, processor, or packer does not hold a valid permit when so required by regulations under section 12.

(7) The refusal to permit access to or copying of any record as required by section 14.

(b) Any person who violates or causes to be violated any of the provisions of paragraph (a) of this section shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not less than $100 nor more than $1,000, or both such imprisonment and fine; and for a second or subsequent offense imprisonment for not more than two years, or a fine of not less than $100 nor more than $3,000, or both such imprisonment and fine.

(c) Notwithstanding the provisions of paragraph (b) of this section, in case of a willful offense the penalty shall be imprisonment for not more than three years, or a fine of not less than $1,000 nor more than $10,000, or both such imprisonment and fine.

(d) No person acting in the capacity of publisher, advertising agency, or radio broadcast licensee shall be deemed in violation of paragraphs (b) or (c) of this

section by reason of the dissemination of any false advertisement. Any such person who, on reasonable request of an officer or employee duly designated by the Secretary, willfully refuses to furnish the name and post-office address of the person who caused him to disseminate such advertisement, shall be guilty of a misdemeanor and shall on conviction thereof be subject to the penalties prescribed in paragraph (b) of this section.

(e) No dealer shall be prosecuted under paragraph (b) of this section if he establishes a guaranty or undertaking signed by the person residing in the United States from whom he received the article of food, drug, or cosmetic, or the advertising copy therefor, to the effect that such person assumes full responsibility for any violation of this Act, designating it, which may be incurred by the introduction of such article into interstate commerce or by the dissemination of such advertising. To afford protection, such guaranty or undertaking shall contain the name and address of the person furnishing such guaranty or undertaking, and such person shall be amenable to the prosecution and penalties which would attach in due course to the dealer under the provisions of this Act.

(f) Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification device required by regulations promulgated for the enforcement of the provisions of section 12 shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine.

(g) Any person who uses to his own advantage or reveals, other than to the Secretary or his officers or employees, any information acquired under authority of sections 12 or 13 concerning any patentable method or process not protected by letters patent, shall be guilty of a felony, and shall on conviction thereof be subject to imprisonment for not more than two years or a fine of not more than $5,000 or both such imprisonment and fine.

LIABILITY OF CORPORATIONS AND THEIR OFFICERS

SEC. 18. (a) When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, or agent acting for or employed by any person, within the scope of his employment or office, shall in every case be deemed to be the act, omission, or failure of such person, as well as that of the officer, employee, or agent.

(b) Whenever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the indivdual directors, officers, or agents of such corporation or association who personally ordered, or did any of the acts constituting, in whole or in part, such violation.

INJUNCTION PROCEEDINGS

SEC. 19. (a) Each of the following acts is hereby declared to be a public nuisance:

(1) The repetitious introduction into interstate commerce of any adulterated or misbranded food, drug, or cosmetic.

(2) The repetitious dissemination of any false advertisement by radio broadcast, United States mails, or interstate commerce for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics.

(3) The repetitious dissemination of a false advertisement by any means for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics in interstate commerce.

(b) In order to avoid multiplicity of criminal or libel for condemnation proceedings, the district courts of the United States are hereby vested with jurisdiction to restrain by injunction, temporary or permanent, any person from continuing any such nuisance. In such injunction proceedings it shall not be necessary to show on the part of such person an intent to continue such nuisance.

(c) Violation of any such injunction may be summarily tried and punished by the court as a contempt. Such contempt proceedings may be instituted by order of the court or by the filing of an information by the United States attorney; and process of the court for the arrest of the violator may be served at any place in the United States or subject to its jurisdiction.

IMPORTS AND EXPORTS

SEC. 20. (a) The Secretary of the Treasury shall deliver to the Secretary of Agriculture upon his request, from time to time, samples of food, drugs, and

cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) any false advertisement of such food, drug, or cosmetic has been disseminated in the United States by the importer or exporter thereof, or any person in privity with him, within three months prior to the date such article is offered for import, or (2) such article has been manufactured, processed, or packed under insanitary conditions, or (3) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (4) such article is adulterated or misbranded within the meaning of this Act, then such article shall be refused admission.

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon, and on refusal to return such article or any part thereof for any cause to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, said consignee shall forfeit the full amount of the bond as liquidated damages.

(c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, or cosmetic intended for export which is not adulterated within the meaning of section 3, paragraph (a); section 4, paragraph (a); or section 5 shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) complies with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the package with the words, "For Export." But if such article is sold or offered for sale in domestic commerce, this paragraph shall not exempt it from any of the provisions of this Act.

PUBLICITY

SEC. 21. The Secretary shall cause to be published periodically a report summarizing all judgments, decrees, and court orders which have been rendered, including the nature of the charge and the disposition thereof. The Secretary shall also cause to be disseminated such information regarding food, drugs, or cosmetics as may be necessary to protect against dange to public health or fraud upon the consumer: *Provided*, That no such information shall be so disseminated regarding any brand of food, drug, or cosmetic before rendition of final judgment in proceedings against it except in cases involving imminent danger to health or gross deception of the consumer.

GENERAL ADMINISTRATIVE PROVISIONS

SEC. 22. (a) The authority to make regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) To aid and advise the Secretary in promulgating regulations for the protection of public health, as contemplated by section 3, subdivision (2) of paragraph (a), and paragraph (d); section 4, dubdivision (2) of paragraph (b); section 5, paragraph (b); section 8, paragraphs (b), (c), and (d), subdivision (1) of paragraph (e), and paragraph (g); section 9, paragraph (c); section 10; and section 12, paragraph (a), a Committee on Public Health is hereby provided which shall consist of five members designated by the President with a view to their distinguished scientific attainment and interest in public health and without regard to their political affiliation.

(c) To aid and advise the Secretary in the promulgation of regulations with respect to food as contemplated by section 7, subdivision (2) of paragraph (a), and paragraphs (d), (e), and (g); and section 11, a Committee on Food is hereby provided which shall consist of five members designated by the President with a

view to their scientific and technical knowledge of food and without regard to political affiliation.

(d) Whenever the Secretary deems that any regulation contemplated by the provisions of this Act enumerated in paragraphs (b) and (c) of this section should be established, he shall so advise the appropriate committee. With the approval of not less than three members, the committee shall recommend to the Secretary a proposed regulation, and the Secretary shall give notice of the proposal and of the time and place of a public hearing to be held thereon not less than thirty days after the date of such notice. After such public hearing the Secretary is authorized to formulate and promulgate such regulation, but no such regulation shall be promulgated without the approval of at least three members of the committee. The regulation so promulgated shall become effective on a date fixed by the Secretary, which date shall not be prior to ninety days after its promulgation, and may be amended or repealed in the same manner as is provided for its adoption: *Provided*, That regulations setting up exemptions pursuant to section 8, paragraph (d), and section 9, paragraph (c) may be promulgated without notice or hearing and shall become effective at such time as the Secretary determines.

(e) The term of office of members of the Committees provided by paragraphs (b) and (c) of this section shall be five years, but the terms of office of the members first appointed shall expire at the end of one, two, three, four, and five years, as shall be designated by the President in their respective appointments. In appointing members to the committees the President shall designate the chairman. No person who is a member of the Department of Agriculture or who has a financial interest in the manufacture, advertising, or sale of any food, drug, or cosmetic shall be eligible to appointment to either committee.

(f) Each committee shall convene at least once each year in the city of Washington at a time to be designated by its chairman, but action by either committee under this section may be taken by the members thereof acting individually without convening in meeting. In each case in which approval by either committee of a regulation is required under this section, the Secretary shall transmit to each member of such committee a transcript of the record of the public hearing held by him. Members of the committees shall be given due notice of, and may sit with the Secretary or his representatives at, all such public hearings relating to the functions of their respective committees. Each committee on its own motion or at the request of the Secretary may advise him of its views on any question concerning the enforcement of this Act.

(g) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 20. Such regulations shall be promulgated in such manner and take effect at such time as the Secretary of Agriculture shall determine.

(h) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose. In formulating regulations under paragraphs (b) and (c) of this section, the findings of fact by the Secretary shall be conclusive if in accordance with law.

COURT REVIEW OF REGULATIONS

SEC. 23. The district courts of the United States are hereby vested with jurisdiction to restrain by injunction, temporary or permanent, the enforcement by any officer or employee of the Department of Agriculture of any regulation promulgated as provided in section 23 if it is shown that the regulation is unreasonable, arbitrary, or capricious, or not in accordance with law, and that the petitioner will suffer substantial damage by reason of its enforcement: *Provided*, That the foregoing shall not be deemed to abridge the right of any person against whom a criminal prosecution or suit for injunction shall have been brought under this Act or who shall intervene as claimant in any proceeding of libel for condemnation to plead that the regulation whose violation is alleged as the ground for such prosecution, suit, or libel, is invalid.

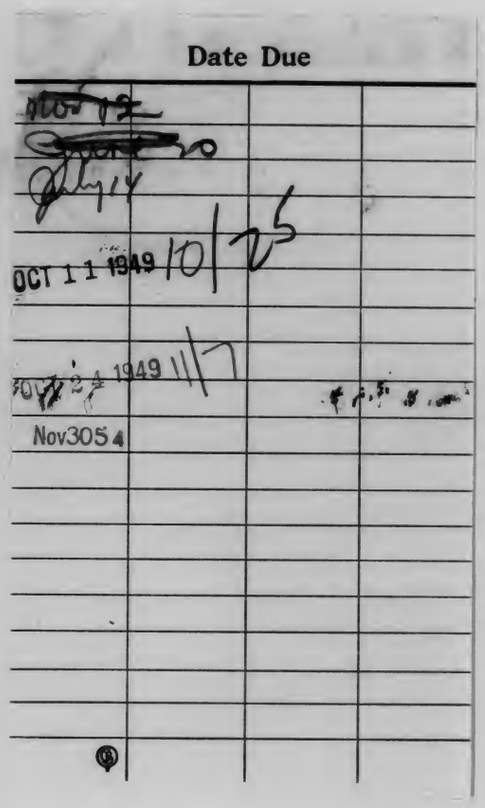
SEPARABILITY CLAUSE

SEC. 24. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATES AND REPEALS

SEC. 25. (a) This Act shall take effect six months after the date of approval. The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., title 21, secs. 1–15), shall remain in force until such effective date, and, except as otherwise provided in this paragraph, is hereby repealed, effective upon such date: *Provided*, That upon the approval of this Act and before its effective date the Secretary is authorized to conduct hearings and to promulgate regulations under the provisions hereof which shall become effective on or after the effective date of this Act as the Secretary shall direct: *Provided further*, That the Act of March 4, 1923 (U.S.C., title 21, sec. 6; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor, and the Act of July 24, 1919 (U.S.C., title 21, sec. 10; 41 Stat. 271, ch. 26), defining wrapped meats as in package form, shall remain in force and effect and be applicable to the provisions of this Act.

(b) The provisions of this Act shall not be held to modify or repeal any of the existing laws of the United States except as provided by paragraph (a) of this section.



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U.S. Cong. Sen. Comm on Comm.
Food, drugs + cosmetics ...

Herman Poldark
Focust Valley, N.Y.
July 14

END OF
TITLE